



DEPARTMENT OF CLINICAL INVESTIGATION

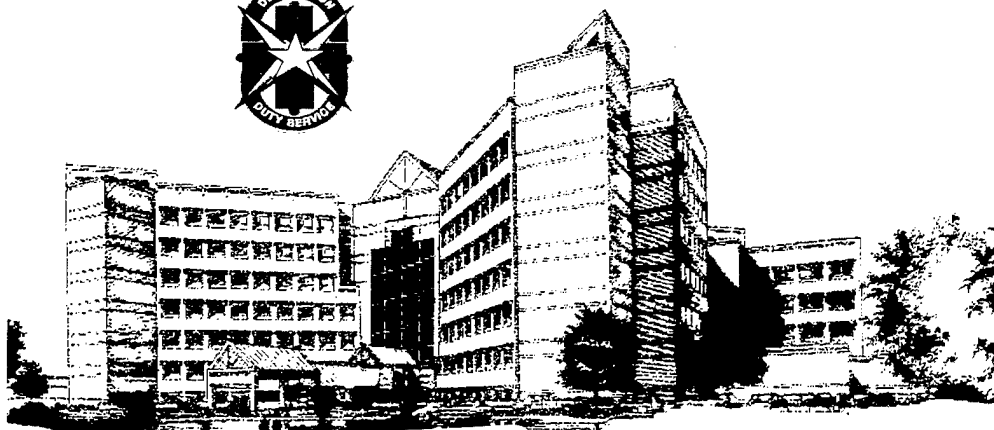
# ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1996  
VOLUME I

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# REPORT DOCUMENTATION PAGE

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13. ABSTRACT (Maximum 200 words)  Subject reports identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Institutional Review Board, and the Animal Use Committee for registration with the Department of Clinical Investigation during Fiscal Year 1996, and known publications and presentations by the Brooke Army Medical Center professional staff. A detail summary sheet of each protocol giving the objective, technical approach and progress is presented.				
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C - Contract	PR - Project
G - Grant	TA - Task
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## ANNUAL REPORT

1996 was a watershed year in the history of Brooke Army Medical Center, BAMC, as it moved from Main Hospital built in 1906 into a fabulous new facility. The Department of Clinical Investigation was privileged to move into the adjoining research building which is also the new home of the Institute of Surgical Research, ISR.

The research facility includes 52,000 square feet of office and basic science labs and a 52,000 square foot vivarium. With the acquisition of the latest sophisticated equipment, the basic science labs provide state of the art biochemistry, immunology, and molecular biology capability. The vivarium operated as a joint facility with the ISR has 42 animal rooms and six operatories with radiology and fluoroscopy capability. The lab animal medicine function is directed by DCI veterinarian, MAJ Vincent Gresham with ISR veterinary staff providing surgical and pathology expertise. This area of research has great growth potential in this new facility.


The DCI stem cell processing lab is colocated with the bone marrow transplant ward and the drug development unit on the fifth floor of the new hospital. This lab under the direction of LTC Seal and Mrs. Barbara Reeb continues to support the clinical oncology mission as well as participate in some very exciting research protocols attempting to store and maintain functioning granulocytes for longer periods of time prior to reinfusion in patients.

The scope of the DCI mission significantly increased in 1996 because of the closure of Fitzsimons Army Medical Center. BAMC thus added responsibility for monitoring research activities at Fort Leavenworth, KS, Fort Sill, OK, Fort Riley, KS, Fort Carson, CO, and the Fitzsimons Army Health Clinic. We continue to serve as the regional consultant for clinical investigation to Fort Sill, Fort Hood, Fort Polk, and Panama as part of the Great Plains Regional Medical Command.

New initiatives this year include the establishment of a DCI position for a Physical Therapy research coordinator for the entire physical therapy branch of the AMEDDC&S. LTC Nancy Henderson has energetically begun working with her physical therapy colleagues to plan and conduct multicenter outcome studies to evaluate a variety of physical therapy modalities.

BAMC applied and was accepted into membership in the Southwest Research Consortium which will foster increased collaboration with scientific and academic research centers in the region. Integration efforts between the Clinical Investigation Directorate, Wilford Hall and our department have made excellent progress through dual efforts of the leadership at each institution. Similar efforts have now begun with the Institute of Surgical Research. These collaborative, cooperative relationships will broaden our capabilities and provide increased opportunities for research for both staff and housestaff.

Contributing to the capability of BAMC Department of Clinical Investigation to accept these new missions has been the addition of a second physician, LTC(P) Arnold Asp, our new assistant department chief, and Mrs. Robbie Fuqua, our second protocol coordinator who will work with Helen Smith. Together with LTC Seal, the department Lab Director, LTC Henderson, MAJ Gresham, our civilian scientists, Dr. Johnson, Dr. Merrill, and Dr. Ward and the entire DCI staff we are elated to be working with the graduate medical education program chiefs in such a great facility. We are very appreciative of the support given to the Department by the Commander, BG Robert Claypool, MC, the Deputy Commander COL William Strampel, MC, and the Chief of Staff, COL Herbert Reamey and COL Joseph Gonzales. We look forward to the coming year of work to support and encourage the academic pursuits of the BAMC staff and housestaff.

  
Jenice N. Longfield LTC(P), MC  
Chief, Department of Clinical Investigation





## COMMANDER'S AWARD WINNERS

### First Place

*Effect of Ambient Temperature on  
Metabolic Rate Following Thermal Injury*

CPT John J. Kelemen, MC  
General Surgery Resident

### Second Place

*Use of Phosphoenolpyruvate Treated Blood to  
Increase Oxygen Availability in the Dog*

LTC Rhonda L.S. Cornum, MC  
Urology Resident

### Third Place

*Independently Obtained Mechanical Characteristics  
of Eight Femoral Intramedullary Nailing Systems*

MAJ Keith D. Wilkey  
Orthopaedic Surgery Resident

\* \* \* \* \*

## UNIT SUMMARY

### FISCAL YEAR 1996

#### A. Objectives:

The objectives of the Department of Clinical Investigation are as follows:

1. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.
2. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.
3. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.
4. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.
5. To maintain a high professional standard and accreditation of advanced health programs.
6. To assure the highest level of professional standards in the conduct of human research and animal research.
7. To offer patients the opportunity to participate in human research endeavors.

#### B. Technical Approach:

All research, investigational and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-3, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

#### C. Staffing:

Name	Rank	MOS	Title
Longfield, Jenice N.	LTC(P)	60C9A	Chief
Asp, Arnold A.	LTC(P)	61E00	Asst Chief
Seal, Lawton A.	LTC	71A	Microbiologist
Henderson, Nancy E.	LTC	65B00	Physical Therapist
Gresham, Vincent C.	MAJ	64A00	Veterinarian
Knopp, Gerald L.	SFC	91K4R	Admin NCO
Irizarry, Zulma	SGT	92B20	Med Lab Specialist
Guzman, Edwin**	SSG	92B30	Med Lab Specialist
White, James A.	SGT	92B30	Med Lab Specialist
Poff, Jennifer L.	SGT	92B10	Med Lab Specialist
Huston, Michelle D.	SPC	91K10	Med Lab Specialist
Ortiz, Ruben	SGT	91T20	Animal Care Specialist
Davis, Reginald	SGT	91T20	Animal Care Specialist
Barajas, Rene C.**	SFC	91T30	Animal Care Specialist
Merrill, Gerald A.	GS12	00401	Research Immunologist

Ayala, Eleanor F.	GS11	00644	Medical Technologist
Ward, John A.	GS13	00401	Research Physiologist
Johnson, Jean M.	GS12	00610	Research Nurse
Reeb, Barbara A.	GS11	00644	Medical Technologist
Stuart, Sandra K.	GS11	00644	Medical Technologist
Fields, Vicki L.	GS11	00644	Medical Technologist
Chapa, Isidoro A.	GS09	00645	Medical Technician
Williams, Dannie J.	GS07	00404	Biological Lab Technician
Rios, Roberto**	GS09	01020	Med Scientific Illustrator
Smith, Helen J.	GS09	00301	Clin Research Protocol Coord
Fuqua, Robbie	GS09	00301	Clin Research Protocol Coord
Aguero, Lynda D.	GS06	01087	Editorial Asst
Johnson, Maurine E.	GS06	00318	Secretary

\* Assigned

\*\* Reassigned

Personnel:	Authorized	Required	Assigned
Officers -	5	9	5
Civilians -	13	16	13
Enlisted -	7	10	7

#### D. Funding:

Type	Fiscal Year 95	Fiscal Year 96
Civilian personnel to include benefits	475,895.72	433,494.58
Supplies/Operation Expenses	161,916.50	221,253.00
Civilian contracts to include consultants	11,171.00	0.00
Noninvestment equipment (Minor MEDCASE)	-----	-----
Other OMA	-----	-----
OMA Total	648,983.22	654,747.58
MEDCASE	103,000.00	125,000.00
CEEP	40,376.00	825,358.00
Other (Bone Marrow Unit)	28,875.45	58,279.00
Military	619,000.00	525,000.00
<b>TOTAL</b>	<b>1,440,234.67</b>	<b>\$2,188,384.58</b>

#### Gifts and Grants:

- a. U.S. Army Medical Research and Development Command - \$137,000.00
- b. Southwest Oncology Group - \$229,000.00
- c. Gynecology Oncology Group - \$25,000.00
- d. Other Nonfederal Gifts - \$128,299.00
- e. NIH - \$133,736.00
- f. Henry M. Jackson Foundation (USUHS/DOD) - \$192,201.00
- g. University of Texas Health Science Center (SPAF) - \$15,888.00
- h. CRDA - \$0.00

## Protocol Disposition FY 96

	HUMAN	ANIMAL
Ongoing	562	32
Completed	91	4
Terminated	60	3
Withdrawn	4	0
	717	39

Number of resident and fellowship programs: 23

Number of residents and fellows with approved protocols: 86

Number of approved protocols held by this group: 134

Other training programs that use Clinical Investigation: University of Texas Health Science Center at San Antonio; University of Texas, Austin; US AMEDD Center and School Physical Therapy Branch.

Number of approved protocols held by this group: 38

Number of hospital staff members with approved protocols: 239

Number of approved protocols held by this group: 493

Drug evaluation/comparison studies: 131 (Does not include Oncology Group Protocols)

There is a continuing requirement to have documented classroom hours devoted to research topics such as ethics, statistics, informed consent, protocol development, etc. These requirements are being met by going to the departments and offering tailored instruction for each unit's needs.

We continue to benefit from gifts and grants offered through the Henry M. Jackson Foundation (HMJF), Facilitators of Applied Clinical Trials (FACT), the National Kidney Foundation (NKF) and other not for profit organizations.

\*\*\*\*\*

Publications and Presentations Reported to Department of Clinical Investigation in 1996:

Publications: 105

Abstracts: 56

Presentations: 127

## **COMMITTEE MEMBERS**

Commander

BG Robert G. Claypool, MC

Chairman

LTC(P) Jenice N. Longfield, MC  
Chief, Clinical Investigation Department

### **Clinical Investigation Committee**

Chief or delegated representative of:  
Department of Clinical Investigation  
Department of Emergency Medicine  
Department of Medicine  
Department of Nursing  
Department of Obstetrics/Gynecology  
Department of Pathology/Area Lab Svc  
Department of Pharmacy  
Department of Radiology  
Department of Surgery

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### **Institutional Review Board**

Chief or delegated representative of:  
Department of Clinical Investigation  
Institute of Surgical Research  
Clinical Investigations, Wilford Hall Med Cen  
Department of Emergency Medicine  
Department of Ministry/Pastoral Care  
Department of Obstetrics/Gynecology  
Department of Pharmacy  
Hematology/Oncology Service  
Center Judge Advocate  
Patient Administration Division  
Ethicist, AMEDD Center & School, Unaffiliated/Non-scientist

## INDEX TO PROTOCOLS

**O = Ongoing**

**T = Terminated**

**C = Completed**

**W = Withdrawn**

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
<b>Department of Clinical Investigation</b>			
C-88-018 Merrill GA	O	Development of an Indirect Chemiluminogenic Enzyme Linked Immuno- assay (CELIA) for Demonstrating Conformation Changes in a Model Protein .....	26
C-91-004 Merrill GA	O	Development of a Bioluminescent Assay of Extreme Sensitivity for Detection and Quantitation of Ricin .....	27
C-93-020 Seal LA	O	Establishment of a Polymerase Chain Reaction (PCR) Nucleic Acid Amplification Capability Within the Department of Clinical Investigation, BAMC .....	28
C-93-095 Longfield JN	O	Inoculation with Pentavalent (ABCDE) Botulinum Toxoid .....	29
C-91-025 Ward JA	O	Automated Screening of Western Blot Densitometer Scans for the Detection of Type-Specific Herpes Virus Antibodies .....	30
C-91-091 Yeager CL	T	Molecular Detection of Bloodborne Pathogens in Blood for Transfusion with Emphasis on Hepatitis C .....	31
C-94-075 Davey E	T	Evaluation of Terry Fox Metho-Cult H433 and Gibco BRL Human Bone Marrow Stem Cell Differentiation Media .....	32
C-95-094 Motil KJ	T	Dietary Protein Needs and Protein and Amino Acid Metabolism of Military Women and Men .....	33
C-95-126 Bradley M	O	Investigation of Possible changes in the Concentration of Soluble Leukocyte Selectin (sL-selectin) in Stored Blood .....	34
C-95-143 Ward JA	O	Design and Evaluation of Rapid Assays for Select Antibody and Antigen Specificities throughout the Course of B Virus Infection .....	35
C-96-045 Seal LA	O	An In Vitro Assessment of the Antineoplastic Potential of 2H-1, 3-Oxazine-2, 6(3H)-Dione (3-Oxauracil) .....	36
C-96-098 Seal LA	O	Metabolic Pathogenesis of Fibromyalgia Syndrome #3. Platelet Serotonin and Spinal Fluid Neuropeptides .....	37

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
<b>Department of Dermatology</b>			
C-93-003 McCollough ML	C	5-Fluorouracil Iontophoretic Therapy for Bowenoid Conditions .....	38
C-93-122 Conger LA	T	A Single Blinded Study Comparing Nightly vs Every Other Night vs Weekly Application of Retin-A 0.05% Cream for the Treatment of Comedonal Acne Vulgaris .....	39
C-94-004 Anderson L	T	Growth of Human Basal Cell Carcinoma Cells in defined Medium and Study of Their Growth and Immunologic Characteristics .....	40
C-94-055 Biediger TL	T	A Single-Blinded Study Comparing Nightly vs Every Other Night vs Weekly Application of Retin-A 0.05% Cream for the Treatment of Comedonal AcneVulgaris .....	41
C-94-095 Angeloni	C	The Effect of Acemannan on UVB-Induced Erythema .....	42
C-95-007 Menon, P	C	A Double Blind Study Comparing EMLA Cream to Iontophoresis of Lidocaine (Xylocaine) for Painless Induction of Cutaneous Anesthesia .....	43
C-95-073 Deering K	O	A Randomized, Single Blind Study to Compare the Cost and Efficacy of Topical Calcipotriene (Dovonex) with that of Topical 5-Fluorouracil (Efudex) for the Treatment of Psoriasis .....	44
C-95-101 Keller RA	O	An Open-label Multicenter Trial to Evaluate the Safety and Effectiveness of Various treatment Durations of Terbinafine in Patients with Onychomycosis of the Toenails .....	45
C-95-111 Grabski WJ	O	A Five-Yr Observational Study to Evaluate Clinical Response and Recurrence Rate in the Treatment of Basal Cell Ca with Fluorouracil/Epi- nephrine Injectable Gel .....	46
C-95-128 Pujals J	O	An Open Label Study to Evaluate the Effectiveness of 1,25 Dihydroxy Vitamin D3 (ROCALTROL) in Patients Who Have Limited or Diffuse Systemic Sclerosis .....	47
C-96-055 Angeloni VL	O	Dermatophyte Flora in an Outpatient Dermatology Clinic .....	48
C-96-095 English JC III	O	Comparison of High energy, Pulsed CO2 Laser vs Q-switched Nd:YAG (1064nm) Laser in the Treatment of Tattoos .....	49

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-96-119 David-Bajar K	O	An Ultrastructural Study of the Dermal-Epidermal Junction following Skin Splitting with Various Methods .....	50
C-96-142 Laws R	O	High-Energy, Short-Pulsed Carbon Dioxide Laser Resurfacing for Prophylaxis and Treatment of Actinic Keratoses .....	51

## **Department of Emergency Medicine**

C-93-040 Hunter C	O	An Evaluation of Nafcillin for the Initial Treatment of Cellulitis .....	52
C-94-010 Hemphill R	O	Comparison of Outpatient treatment for Pyelonephritis .....	53
C-94-035 Gerhardt RT	C	HOOD Evaluation of Albuterol Metered Dose Inhaler Effects on Serum Potassium Levels in Healthy Adults: A Prospective Study .....	54
C-95-036 Hemphill RR	C	Follow-up Compliance for Febrile Children .....	55
C-95-127 Brooks M	O	Use of H1/H2 Blockers in Treatment of Acute Urticaria .....	56
C-96-064 Davison M	O	Is Haloperidol an Effective Treatment for Patients Presenting with Migraine Headaches to the Emergency Department? .....	57
C-96-090 Colo AJ	O	Diagnostic Efficacy of Troponin T in diagnosing Acute MI and Correlation of Positive Troponin T Levels in Patients with Acute MI and Unstable Angina with Incidence of In-hospital Complications .....	58
C-96-091 Buggs AM	O	A Retrospective Review of Emergency Department Right Upper Quadrant Ultrasounds .....	59

## **Department of Medicine, Cardiology Service**

C-91-013 Moody J	O	A Randomized, Double-Blind, Placebo-Controlled Trial of the Effect of Livastatin on the Incidence of Primary Coronary Artery Disease in Patients with Mild to Moderate Elevations in Total and LDL-Cholesterol in Combination with Low HDL-Cholesterol .....	60
C-93-39 Boyd S	C	Relationship of Echocardiographic Doppler Indices of Diastolic Function to Severity of Cardiac Transplant Rejection .....	61



<b><u># and PI</u></b>	<b><u>Status</u></b>	<b><u>Title</u></b>	<b><u>Page</u></b>
C-93-041 Ebersole DG	T	An Evaluation of Radionuclide Angiography and Echocardiography for Assessment of Doxorubicin Induced Ventricular Dysfunction .....	62
C-93-047 Rubal B	O	Validation of a Nonlinear Three Element Model for Estimating Stroke Volume and Aortic flow Wave from Morphology in Man .....	63
C-93-065 Miller L	C	Effect of Supportive Interventions on Patient Perception of Musculoskeletal Pain During Cardiac Catheterization .....	64
C-93-066 Miller L	T	Myocardial Imaging Utilizing Positron Emission Tomography to Detect and Assess Coronary Artery Disease .....	65
C-93-115 Bauch T	T	Obstructive Sleep Apnea and Silent Myocardial Ischemia in Post-Myocardial Infarction Patients; Frequency, Temporal Relationship and Response to Nasal Continuously Positive Airway Pressure (nCPAP) Therapy .....	66
C-93-125 Ebersole D	T	Endosconics PTCA Balloon Catheter: Eagle .....	67
C-94-019 Moody JM	O	Time-Frequency Analysis of Phonocardiograms: A Study of Prosthetic Heart Valve Sounds .....	68
C-94-022 Do TM	T	Time-Frequency Analysis of ECK in Patients Post-Myocardial Infarction and at Risk for Sudden Death .....	69
C-94-027 Mego D	O	Percutaneous Transluminal Coronary Angioplasty vs Coronary Stenting of De Novo Saphenous Vein Bypass Grafts .....	70
C-94-043 Champ JD	C	Comparison of Newer Doppler-Echocardiographic Methods for the Quantification of Mitral Regurgitation .....	71
C-94-057 Moody JM	C	Blood Velocity, Valve Leaflet Flutter and Murmurs in Normal Teenagers .....	72
C-94-143 Mego D	T	Thrombus Formation During coronary Angioplasty in Acute Ischemic Syndromes: Influence of Contrast Media .....	73
C-95-001 Boyd S	O	Stroke Prevention in Atrial Fibrillation III (SPAF III) .....	74
C-95-016 Malinowski TR	C	Serum CK Response to Endomyocardial Biopsy .....	75

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
C-95-048 Furgerson JL	O	A Comparison of Stress Echocardiography, Dobutamine Echocardiography, and Adenosine Sestamibi SPECT Perfusion Imaging for Detection of Coronary Artery Disease in Patients with Left Bundle Branch Block .....	76
C-95-057 Rollefson WA	O	Assessment of Myocardial Viability using the Doppler Flo-wire and Low Dose Dobutamine .....	77
C-95-090 Zimring HJ	O	Coronary Blood Flow Hemodynamics in Normal Patients Measured with the Doppler Flo-Wire .....	78
C-95-095 Zimring HJ	O	Assessment of Myocardial Viability using the Doppler Flowwire and Positron Emission Tomograph in Chronic Coronary Artery Disease Patients ...	79
C-95-113 Boyd S	O	CARES Study Cardiac Risk Evaluation with Exercise Echo Cardiography Stress Testing .....	80
C-95-120 Bauch TD	C	Utility of Digital Acoustic Cardiography for the Evaluation of Heart Murmurs .....	81
C-95-130 Mego D	O	A Phase II, Placebo-Controlled Multicenter Study of TLC C-53 as an Adjunct to Thrombolytic Therapy in Patients with Acute Myocardial Infarction .....	82
C-96-004 Mego DM	O	A Randomized, Double-Blind Evaluation of the Efficacy and Safety of Two Dosing regimens of Integrelin vs Placebo for Reducing Mortality and (Re) Infarction in Patients with Unstable Angina or Non-Q Wave Myocardial Infarction .....	83
C-96-005 Flaherty PJ	O	Heart Rate Variability as a Predictor of Clinical Response to Beta-Adrenergic Blockade in Patients with Idiopathic Dilated Cardiomyopathy .....	84
C-96-028 Mego D	O	Reduced Anticoagulation for Stenting in Native Coronary Arteries .....	85
C-96-043 Mego D	O	Stent Anti-thrombotic Regimen Study (STARS) .....	86
C-96-053 Ebersole DG	O	Reduced Anticoagulation After Vein Graft Stenting (RAVES) .....	87
C-96-067 Gilman JK	O	Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) .....	88
C-96-071 Miller L	O	The Effect of a Prototype Mattress and Arm Positioning Techniques on Musculoskeletal Back and Arm Pain During Invasive Cardiac Procedures .....	89

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-96-072 Mego D	O	A Pilot Study of Local Delivery of Heparin During PTCA for Acute Myocardial Infarction .....	90
C-96-081 Harrington K	O	Troponin T as a Non-invasive Marker of Rejection in Heart Transplant Patients .....	91
C-96-111 Edavettal JM	O	Is There a role for Limited Echocardiography? .....	92

### **Department of Medicine, Endocrinology Service**

C-88-019 Thomason AM	T	Effect of Oral Agents vs Insulin Therapy on Lipid Profile .....	93
C-92-014 Carlin K	C	Cell Culture Model to test the Relative Independence of Cancer Cells to Reduced T3 Levels by Comparison to More Normal Cells .....	94
C-92-041 Carlin K	O	Quantification of T3 Receptors in Human Cancer Tissue Compared to the Same Surgical Specimen .....	95
C-92-085 Carlin K	O	Possible Hormone Manipulations in the Treatment of HIV Infections in Cell Culture Medium .....	96
C-92-098 Carlin K	O	Investigation of a Possible Etiology for Euthyroid Sick Syndrome .....	97
C-93-037 Carlin K	O	Proposal for a Research Model to Investigate Possible Hormone Manipulations in the Treatment of HIV Infections Using Variations in Cell Culture Medium to Test for Facilitators and Inhibitors from the Hormone Family (Part II) .....	98
C-94-049 Carlin K	O	Cell Culture to Test if MCF-7 Breast Cancer Cells in Vitro are Independent of Thyroid Hormone .....	99
C-94-051 Carlin K	O	The Effect of Tetrac and Triac Upon murine Bladder Cancer Cells in Cell Culture .....	100

### **Department of Medicine, Gastroenterology Service**

C-92-011 Kadakia S	C	Household Transmission of Hepatitis C Virus in Military Populations .....	101
C-92-030 Shaffer R	O	Regression of Metaplastic Esophageal Epithelium with Omeprazole .....	102

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
C-92-094 Kadokia S	O	Phase II - Colon Carcinogenesis: Modulation by Dietary Intervention .....	103
C-93-001 Fedalei A	O	Does Cholecystikinin (CCK) Prevent Gallbladder Sludge or Gallstone Formation in Patients Receiving Parenteral Nutrition .....	104
C-93-005 Shaffer RT	O	A Comparison Study of Acute Aspirin Induced Gastrodudenal Injury with Omeprazole vs Misoprostol .....	105
C-93-006 Kadokia S	O	Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas .....	106
C-93-008 Carrougher JG	T	Endosonosopic Evaluation of Helicobacter Pylori Associated Gastritis .....	107
C-93-012 Angueira CE	C	ASGE Survey: Anticoagulation and GI Endoscopy .....	108
C-93-026 Kadokia SC	C	Effect of Intravenous Erythromycin on Gastric Emptying in Patients with Anorexia Nervosa or Bulimia .....	109
C-93-043 DeLaBaume HR	C	Effects of the Nicotine Patch on Esophageal Motility .....	110
C-93-064 Buckner CA	C	Effect of Omeprazole on Blood Alcohol Levels After Oral and Intravenous Ethanol .....	111
C-94-044 Kadokia SC	O	Effect of Intravenous Erythromycin on Gastric Emptying in Patients with Billroth I or Billroth II Anastomosis .....	112
C-94-109 Farrington CA	C	Gastric Hyposecretion in Patients with Walter Reed Stage 6 HIV-1 Infection .....	113
C-94-129 Kadokia SC	C	Evaluation of the Clinical and Cost Effectiveness of Therapy with Clarithromycin Plus Omeprazole Compared to Omeprazole or Ranitidine for the Treatment of Patients with Duodenal Ulcer and Helicobacter Pylori Infection .....	114
C-95-017 Fedalei AG	O	Evaluation of the String Test (Enterotest) for Diagnosing Helicobacter Pylori Infection .....	115
C-95-075 Tanner PE	O	Regression of Barrett's Esophagus After Nissen Fundoplication .....	116

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-95-076 Pfanner TP	C	Concentrations of Methane & Hydrogen in Colonic Gas During Colonoscopy after Preparation of the Colon with Prospo-soda buffered Oral Saline Laxative Solution .....	117
C-95-088 Howden JK	O	Use of Intravenous Erythromycin in Acute Upper Gastrointestinal Hemorrhage .....	118
C-95-096 Tanner PE	C	Golytely bowel Prep - Does Cisapride Help? .....	119
C-95-115 Kadokia SC	O	Multicenter Trial of Oral Ursodeoxycholic Acid vs Combination Ursodeoxycholic Acid Plus Low Dose Oral Pulse Methotrexate Therapy for Primary Sclerosing Cholangitis .....	120
C-96-023 Kadokia SC	O	Aspirin, Nabumetone and Colonic Proliferation .....	121
C-96-026 Wong PWK	O	Effect of Nicotine on Gastric Emptying of Solid and Liquid Contents in Healthy Subjects .....	122
C-96-056 Wong PWK	O	Ursodeoxycholic Acid and Alpha-Interferon Combined Treatment for Chronic Viral Hepatitis Type B and Type C .....	123
C-96-101 Szykowski RD	O	Sublingual Administration of the Anti Spasmodic Agent Levsin as Premedication for Flexibl Sigmoidoscopic Examination .....	124
C-96-102 Szykowski RD	O	Determination of the Frequency of Occurrence of Short Segment Barrett's in Children and Adolescents .....	125
C-96-103 Szykowski RD	O	Determination of the Frequency of Occurrence of Short Segment Barrett's Epithelium by Age Group and Longitudinal Follow-up for Progression After India Ink Tattooing .....	126
C-96-104 Szykowski RD	O	Determination of the Frequency of Occurrence of Short Segment Barrett's Epithelium in Patients with Treated Achalasia .....	127
C-96-136 Wong PWK	O	Optimization of Bowel Preparation with Overnight Magnesium Citrate Prior to Flexible Sigmoidoscopy .....	128

### **Department of Medicine, General Medicine Service**

C-94-072 Marple R	O	Comparison of Cost Effectiveness of Visual Blood Glucose Monitoring and One Touch in an Outpatient Diabetic Clinic: Effects on Glycosylated Hemoglobin .....	129
----------------------	---	--	-----

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
<b>Department of Medicine, Hematology-Oncology Service</b>			
C-87-052 Myhand RC	O	Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma, Using Ex-Vivo Marrow Treatment with 4-Hydroperoxycyclophosphamide (4-HC) .....	130
C-87-062 Myhand RC	O	Autologous Stem Cell Transplant Master Protocol .....	131
C-90-071 Myhand RC	O	High Dose Chemotherapy with Autologous Bone Marrow Support for Selected Advanced Solid Tumors .....	132
C-90-090 Myhand RC	O	Intensive Therapy and Autologous Bone Marrow Transplant with 4-HC Purging in Acute Myelocytic Leukemia (AML) and Acute Lymphocytic Leukemia (ALL) .....	133
C-93-019 Jenkins TR	O	An Open Protocol for the Use of Anagrelin (Anagrelide) for Patients with Thrombocythemia .....	134
C-93-052 Burris HA III	C	Gemcitabine as Palliative Therapy in Patients with Progressive Carcinoma of the Pancreas .....	135
C-93-083 Myhand RC	O	High-Dose Taxol, Cyclophosphamide, and Cisplatin (Taxol/CPA/cDDP) with Autologous Bone Marrow Support (ABMS) for Metastatic Breast Cancer ..	136
C-93-104 Burris HA III	C	Phase I Trial of VP16 + AMGEN rG-CSF in Patients with Advanced Malignancies .....	137
C-93-117 Burris HA III	O	A Phase II Study of Gemcitabine in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit .....	138
C-93-129 Burris HA III	O	A Phase II Study of MGBG in Patients with Hormone Refractory Prostate Cancer .....	139
C-93-133 Burris, HA III	O	A Phase II Trial of RP 56976 in Patients with Cholangiocarcinoma .....	140
C-94-008 Burris HA III	O	Elimination of Extrachromosomal DNA from Ovarian Cancer Patients' Tumors with Hydroxyurea Treatment .....	141
C-94-023 Burris HA III	C	A Phase I Study of AM-285 Administered Via the Intraperitoneal Route in Patients with Intraperitoneal Predominantly Tumor Disease .....	142
C-94-024 Rinaldi DA	C	A Phase I Trial of LY231514 Administered as a Bolus Given Intravenously Every 21 Days .....	143

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
C-94-025 Burris HA III	C	A Phase I/II Dose-Escalating Study of Intravenously Administered Tirapazamine (WIN 59075) in Combination with Cisplatin, in Patients with Non-Small Cell Lung Cancer .....	144
C-94-036 Burris HA III	C	A Phase I Trial of Losoxantrone in Combination with Paclitaxel in Patients with Refractory Malignancies .....	145
C-94-037 Burris HA III	T	The Effect of h Corticotrophin-Releasing Factor on Peritumoral Brain Edema, A Pilot Study .....	146
C-94-038 Burris HA III	O	Phase 2 Double/Blind, Randomized Study of Recombinant Human Interleukin 11 (NEUMEGA rhIL-11 Growth Factor) at Doses of 25 and 50 mcg/kg/d vs Placebo in Adult Cancer Patients with Severe Thrombocytopenia Due to Chemotherapy .....	147
C-94-039 Burris HA III	O	Phase I Clinical and Pharmacokinetic Evaluation of LY 295501 Administered Orally on a Weekly Schedule in Patients with Metastatic Cancer .....	148
C-94-042 Burris HA III	O	A Phase I Trial of Paclitaxel; (IVX-T-101) Administered as a Three-Hour Infusion in Patients with Refractory Non-Small Cell Lung Cancer .....	149
C-94-053 Myhand RC	O	A Randomized Clinical Trial Evaluating Topical Vitamin E Oil in the Treatment of Chemotherapy Induced Mucositis .....	150
C-94-059 Burris HA III	O	A Phase I Trial of Navelbine in Combination with Estramustine in Patients with Hormone Refractory Prostate Cancer .....	151
C-94-064 Burris HA III	C	Double Blind, Parallel Group Explatory Study Comparing the Efficacy and Safety of Tpitriol (Topical Calcitriol) with that of Vehicle in the Protection from Chemotherapy Induced Hair Loss, in Patients with Breast Cancer .....	152
C-94-066 Burris HA III	C	An Open Label, Multicenter, Phase I/II, Dose Escalating Tolerance and Safety Study of Glycosylated Recombinant Human Interleukin-6 (r-hIL-6) in Patients Receiving Chemotherapy .....	153
C-94-068 Rinaldi DA	C	A Phase I/II Study of SDZ PSC 833 with doxorubicin, Vincristine, Cyclophosphamide and Prednisone in Patients with Refractory or Relapsed Non-Hodgkin's Lymphoma .....	154
C-94-069 Burris HA III	O	Phase II Trial of Taxotere in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit .....	155

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
C-94-082 Burris HA III	O	A Randomized, Double-Blind Study Comparing Megace Plus Hydroxyurea to Megace Plus Placebo in Patients with Advanced Cancer .....	156
C-94-085 Burris HA III	O	A Phase I Study of Docetaxel (RP56976) and 5-Fluorouracil Combination Chemotherapy in Patients with Advanced Solid Tumor .....	157
C-94-086 Burris HA III	C	Serum Collection study on Patients with Active Colon or Breast Cancer .....	158
C-94-090 Moretta BJ	C	Cognition, Depression, Quality of Life, and Will-to-Live in Lung Cancer Patients .....	159
C-94-099 Burris HA III	C	A Phase I Study to Determine the Maximum Tolerated Dose of Topotecan Following Oral Administration Over 10 to 21 Days in Patients with Malignant Solid Tumors .....	160
C-94-112 Myhand RC	O	Phase II Study: Treatment of Lymphoma with High-Dose Chemotherapy Consisting of BCNU, Cytosan, and VP-16 with Autologous Stem Cell Support .....	161
C-94-126 Burris HA III	C	A Pilot Study of docetaxel (RP 56976) in Patients with Paclitaxel-Resistant Advanced Breast Cancer .....	162
C-94-130 Jenkins TR	C	Spanish Translation and Validation of a Quality of Life Questionnaire .....	163
C-94-146 Burris HA III	O	A Phase III Trial of Crisnatol Mesylate vs BCNU in the Consolidative Treatment of Glioblastoma Multiforme .....	164
C-94-153 Burris HA III	C	An Open-Label, Multicenter, Non-Comparative, Study of Topotecan as Single Agent, Second-Line Therapy (Administered Intravenously as Five Daily Doses Every 21 Days) in Patients with Small Cell Lung Cancer .....	165
C-95-005 Myhand RC	C	A Phase II Pilot Study of the Antiemetic Effectiveness of IV Granisetron in Patients Receiving Preparative High Dose Chemotherapy Prior to Autologous Bone Marrow Transplantation .....	166
C-95-013 Myhand RC	O	High-Dose Chemotherapy with or without Total Body Irradiation with Autologous Stem Cell support and Alpha-Interferon Consolidation in the Treatment of Patients with Non-Hodgkin's Lymphoma with a Poor Prognosis ..	167
C-95-023 Burris HA III	O	Phase I Trial of Crisnatol Mesylate on an Increasingly Prolonged Continuous Infusion Schedule in Patients with Refractory Malignancies .....	168
C-95-024 Burris HA III	O	A Phase I Trial of Paclitaxel and Gemcitabine in Patients with Refractory Solid Tumors .....	169



<b><u># and PI</u></b>	<b><u>Status</u></b>	<b><u>Title</u></b>	<b><u>Page</u></b>
C-95-025 Burris HA III	C	Phase Evaluation of MGBG in Patient with Refractory or Relapsed Non-Hodgkin's Lymphoma Associated with Acquired Immunodeficiency Syndrome .....	170
C-95-026 Burris HA III	C	A Phase II Study to Evaluate the Combination Chemotherapy Regimen of Irinotecan HCl (CPT-11) Plus Cisplatin in Patients with Inoperable Non-Small Cell Lung Cancer (NSCLC) .....	171
C-95-027 Burris HA III	O	A Phase I Study of the Pharmacokinetics, Safety and Tolerability of Single and Combination Administration of VX-710 in Patients Receiving Single Agent Therapy with Paclitaxel .....	172
C-95-028 Burris HA III	O	A Phase I Escalating-Dose Study to Evaluate the Safety and Pharmacokinetics of a Five-day Regimen of Intravenous 1843U89 Alone and in Combination with High-Dose Oral Folic Acid .....	173
C-95-029 Rinaldi DA	O	A Phase I Study to Determine the Safety of LU 103793 as a 5-Min IV Infusion, Daily x 5, Given Every 3 Weeks to Patients with Malignant Solid Tumors .....	174
C-95-030 Burris HA III	C	A Phase II Study to Evaluate Alternating Cycles of Irinotecan HCl (CPT-11) and 5-Fluorouracil (5-FU) Plus Leucovorin (LV) in Patients with Metastatic Colorectal Cancer .....	175
C-95-038 Burris HA III	O	Phase I Trial to Determine the Maximum Tolerated Dose of Irinotecan Hydrochloride (CPT-11) Using an Every-Other-Week Dosing Schedule in Patients with Advanced Solid Tumor Malignancies .....	176
C-95-039 Burris HA III	C	A Phase I/II Trial of 5-Ethynyluracil (776C85) Plus 5-Fluorouracil in Patients with Solid Tumors .....	177
C-95-046 Burris HA III	C	Chemoimmunotherapy of Metastatic Renal Cell Carcinoma with Interleukin-2, Interferon - $\alpha$ 2B, and 5-Fluorouracil (#IS-L2001) .....	178
C-95-071 Burris HA III	O	A Phase I Study to Evaluate Orally-Administered Irinotecan HCl (CPT-11) Given Daily x 5 Every 3 Weeks in Patients with Refractory Malignancies .....	179
C-95-093 Burris HA III	O	Phase I trial of Gemcitabine Plus Hydroxyurea in Patients with Refractory Solid Tumors .....	180
C-95-099 Burris HA III	O	A Multicenter Randomized Phase III Study of Docetaxel (RP 56976, Taxotere) vs Best Supportive Care in Patients with Non-Small Cell Lung Cancer Previously Treated with Platinum-Based Chemotherapy .....	181

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
C-95-100 Burris HA III	O	A Phase I Trial and Pharmacokinetic Study of the Sequential Administration of Carmustine (BCNU) and Temozolomide in Patients with Advanced Refractory Solid Tumors or Refractory Lymphoma .....	182
C-95-108 Burris HA III	C	Treatment IND of Gemzar (Gemcitabine) for Patients with Pancreatic Cancer .....	183
C-95-110 Atkins MY	O	An Open-Label, Multicenter, Randomized, Ph III Study of Hycamtin (Topotecan) as Single Agent, 2nd-Line Therapy (Admin IV as 5 Daily Doses Every 21 Days) vs 2nd-line CAV in Patients w/SCLC who have Relapsed at Least 3 Months after Completion of First Line Therapy .....	184
C-95-118 Burris HA III	O	A Phase I Study of NSC 655649 Given by Bolus Infusion Every 21 Days .....	185
C-95-122 Atkins MY	O	Letrozole (CGS 20267) Comparison of Two Doses (0.5 mg and 2.5 mg) of Letrozole (CGS 20267) vs Megestrol Acetate in Postmenopausal Women with Advanced Breast Cancer - Protocol 02 .....	186
C-95-124 Aylesworth CA	O	Phase I Trial of Pivaloyloxymethylbuyrate (AN-9) as a 6 Hr Continuous Infusion Daily for 5 Days .....	187
C-95-125 O'Rourke T	T	A Double-Blind, Randomized, Phase 3, Multicenter Study of Suramin and Hydrocortisone vs Hydrocortisone and Placebo in the Treatment of Patients with Metastatic, Hormone Refractory Prostate Ca (Stage D2) (Protocol 1003-01) .....	188
C-95-136 Cobb PW	C	A Phase II Study to Evaluate a 5-Day regimen of Oral 5-Fluorouracil 95FU) Plus 77685 Colon .....	189
C-95-141 Myhand RC	O	Autologous Granulocyte Infusions as Supportive Therapy in Breast Cancer Patients Receiving High Dose Chemotherapy with Stem Cell Support .....	190
C-96-007 Burris HA III	C	Repeat Oral Dose, Dose-Rising Study of the Safety, Tolerability, Pharmacologic Effect of SK&F 107647 in Patients with Solid Tumor Malignancies .....	191
C-96-008 Burris HA III	C	A Phase 2 Trial of LY231514 Administered Intravenously Every 21 Days in Patients with Pancreatic Cancer .....	192
C-96-009 Burris HA III	O	A Phase 2 Trial of LY231514 Administered Intravenously Every 21 Days in Patients with Metastatic Colorectal Cancer .....	193
C-96-012 Burris HA III	C	The Measurement of DT-Diaphorase in Normal Volunteers and Colon Cancer Patients .....	194

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
C-96-019 Burris HA III	O	A Phase I Study of Capecitabine (Ro 09-1978) when Combined with Paclitaxel (Taxol) in Patients with Advanced Solid Tumors .....	195
C-96-020 Burris HA III	O	A Phase II Study of Temozolomide (SCH52365) Prior to Radiation Therapy in the Treatment of Patients with Brain Metastases from Malignant Melanoma .....	196
C-96-024 Aylesworth C	O	A Phase I Clinical and Pharmacokinetic Evaluation of LY309887 Administered Every 21 Days in Patients with Metastatic Cancer .....	197
C-96-025 Burris HA III	O	A Phase I Study of the Safety of Four, Weekly 24-Hour Infusions of Escalating Doses of SU101 in Patients with Solid Tumors .....	198
C-96-027 Burris HA III	O	Phase II/III Trial of 3-Hour Infusions of Paclitaxel from NaPro/ Baker Norton in Patients with Refractory Breast Cancer, and a Preliminary Assessment of 96-Hour Infusions .....	199
C-96-030 Burris HA III	O	A Phase II/III Trial of 3-Hr Infusions of Paclitaxel from NaPro/ Baker Norton in Patients with Refractory Ovarian Cancer with Crossover to a 96-Hr Infusion on Failure .....	200
C-96-050 Burris HA III	O	A Phase II, Open-Label Study of Liarzole in Patients with Advanced Squamous Cell Carcinoma of the Cervix .....	201
C-96-051 Burris HA III	O	A Phase I Trial of a Fixed Dose of PN401 as a Rescue Agent for Escalating Doses of 5-Fluorouracil (5FU) in the Treatment of Patients with Cancer Refractory to Standard Therapy: Weekly x 3 Schedule .....	202
C-96-052 Burris HA III	O	A Phase I Study of Temozolomide (SCH 52365) in Combination with Cisplatin in Patients with Advanced Cancer .....	203
C-96-074 Burris HA III	O	Single Rising Dose Every 3 Weeks, Open Label Study to Demonstrate the Safety, Tolerability, Pharmacokinetics and Preliminary Activity of MDL 101,731 in Patients with Refractory Malignant Solid Tumors .....	204
C-96-075 Burris HA III	O	A Phase I Multiple-Dose, Dose-Escalation Trial of MDL 101,731 Given as a Weekly Intravenous Infusion .....	205
C-96-078 Burris HA III	C	Irinotecan (CPT-11):Phase II, Open-Label, Prospective Evaluation of Age as a Risk Factor for Development of Toxicities in Patients with 5-Fluorouracil Refractory Colorectal Cancer .....	206
C-96-079 Burris HA III	O	A Pilot Study to Determine the Usefulness of Phosphatidic Acid and Serum Acyl Chain Ratios for Assessing Response to Chemotherapy .....	207

<b><u># and PI</u></b>	<b><u>Status</u></b>	<b><u>Title</u></b>	<b><u>Page</u></b>
C-96-82ot Burris HA III	C	Phase I-II Evaluation of DTIC in the Treatment of Malignant Primary Brain Tumor on a Single Dose Schedule (One-Time) .....	208
C-96-086 Burris HA III	C	A Phase I Study to Determine the Safety, Tolerance, Pharmacokinetics kinetics, and Pharmacodynamics of Recombinant Human Thrombopoietin (rhTPO) in Patients with Malignant Neoplasm Receiving Thiotepa .....	209
C-96-087 Burris HA III	O	A Randomized, Dbl-Blind, Placebo Controlled Study to Evaluate the Effect of Cisplatin/Epinephrine Injectable Gel (Product MPI 5010) when Admin Intra-tumorally for Achievement of Treatment Goals in Recurrent or Refractory Squamous Cell Ca of Head & Neck .....	210
C-96-088 Burris HA III	C	A Phase I Study to Determine the Safety, Tolerance, Pharmacokinetics and Pharmacodynamics of Recombinant Human Thrombopoietin (rh TPO) in Patients with Malignant Neoplasm Receiving Thiotepa .....	211
C-96-124 Burris HA III	O	Phase I Study of Dexrazoxane Given in Combination with Doxorubicin with Paclitaxel in Patients with Advanced Refractory Solid Tumors .....	212
C-96-127 Burris HA III	O	A Phase I Evaluation of Intravenous MGI 114 Given Daily for Five Days Twenty-eight Days in Patients with Advanced Cancer .....	213
C-96-129 Burris HA III	O	Irinotecan (CPT-11) - Phase I Study in Refractory Solid Tumor Patients with Hepatic Dysfunction .....	214
C-96-130 Burris HA III	O	A Phase I Study of BMS-182248-01 (BR96-Doxorubicin Conjugate) Administered Five Times a Week in Patients with Advanced Carcinoma .....	215
C-96-131 Burris HA III	O	An Open-Label, Phase 1/2 Ascending Dose Trial of SD MKT 077 to Evaluate the Safety, Tolerability and Pharmacokinetic Profile of Single Weekly Doses Administered by IV Infusion Over 30 Minutes in Patients with Refractory Solid Tumors .....	216
C-96-132a Myhand BC	O	High-Dose Chemotherapy: A Double Bone Marrow Transplant Study for Patients with Metastatic Breast Cancer .....	217
C-96-132b Myhand BC	O	High-Dose Etoposide, Cyclophosphamide and Carboplatin (VP-16, CPA, CBDCA) with Autologous Stem Cell Rescue (ASCR) and Autologous Granulocyte Infusions for Metastatic Breast Cancer - Part II .....	218
C-96-132c Myhand BC	O	Autologous Granulocyte Infusions as Supportive Therapy in Breast Cancer Patients Receiving High Dose Chemotherapy with Stem Cell Support .....	219
C-96-133 Burris HA III	O	Phase I Clinical and Pharmacokinetic Study to Determine the Safety of Ecteinascidin-743 (ET-743) Administered as a Daily Times Five Intravenous Infusion Every 21 Days in Patients with Solid Tumors .....	220

<b><u># and PI</u></b>	<b><u>Status</u></b>	<b><u>Title</u></b>	<b><u>Page</u></b>
C-96-134 Burris HA III	O	Phase I Study to Determine the Safety of LU 79553 as a 30 Minute Intravenous Infusion Every Day x5, Given Every 3 Weeks to Patients with Malignant Solid Tumors .....	221
C-96-139 Burris HA III	C	Irinotecan Hydrochloride (CPT-11): Phase II Trial Using an Every-Other-Week Dosing Schedule in Patients Previously Treated with 5-FU for Colorectal Cancer .....	222
C-96-145 Burris HA III	O	A Phase I Study of Docetaxel (RP 56976) and Doxorubicin Combination Chemotherapy in Patient with Advanced Solid Tumors .....	223
Pending Burris HA III	O	Phase I Study of Taxotere (Docetaxel, RP 56976) for Cancer Patients with Liver Dysfunction Due to Malignancies .....	224
Pending Burris HA III	O	Phase I Study of Dexrazoxane Given in Combination with Doxorubicin and Paclitaxel in Patients with Advanced Refractory Solid Tumors .....	225
Pending Aylesworth CA	O	Phase I Trial of Rhizoxin (NSC 332598) Administered as a 72-Hour Continuous Intravenous Infusion Every 21 Days .....	226
Pending Burris HA III	O	Irinotecan Hydrochloride (CPT-11): Phase II Trial Using an Every-Other-Week Dosing Schedule in Patients Previously Treated with 5-FU for Colorectal Cancer (M6475/0033) .....	227
Pending Burris HA III	O	Phase I Evaluation of CGP 64128A (ISIS 3521) Administered as a Two Hour Intravenous Infusion Three Times per Week, for Three Consecutive Weeks, in Patients with Cancer .....	228
Pending Rinaldi DA	O	A Phase I Trial of Gemcitabine Plus Vinorelbine Combination Therapy in Patients with Refractory Solid Tumors .....	229
Pending Rinaldi DA	O	Phase I Trial of Rhizoxin (NSC 32598) Administered as a 72-Hr Continuous Intravenous Infusion Every 21 Days .....	230
Pending Rinaldi DA	O	A Phase I Protocol to Determine Safety, Tolerability, Pharmacokinetics and Maximum Tolerated Dose of CGP 48664 in Cancer Patients .....	231
Pending Rinaldi DA	O	Phase I Study to Determine the Safety of LU 103793 as a 5-Min IV Infusion, Every Other Day x 3, Given Every 3 Weeks to Patients with Malignant Solid Tumors .....	232
Pending Rinaldi DA	O	A Phase I Dose Finding Clinical Trial to Evaluate the Safety and Pharmacokinetics of DMP 840 in Combination with Cisplatin Given Every Three Weeks (Q3W) in Patients with Advanced Cancer .....	233

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
Pending Burris HA	O	A Phase I Trial of Bizelesin (NSC 61529) Using a Single Dose (10 minute infusion) Given Every 28 Days in Patients with Advanced Cancer .....	234
Pending Burris HA	O	A Phase I, Open Label, Ascending Dose Study of Vesnarinone in Combination with Gemcitabine in Patients with Advanced Cancer .....	235
Pending Burris HA	O	Phase I Trial of LY231514 Given with Folic Acid Supplementation in Patient with Locally Advanced or Metastatic Cancer .....	236
Pending Aylesworth C	O	Compassionate Use Mitoguazone Dihydrochloride in Refractory or Relapsed Non-Hodgkin's Lymphoma--Non-AIDS Related .....	237
Pending Burris HA	O	Extended Administration of Temozolomide (Sch 52365) in Patients with Advanced Cancer .....	238
Pending Burris HA	O	A Phase I Study of LY231514 and 5-Fluorouracil in Patients with Locally Advanced or Metastatic Cancer .....	239

## **Department of Medicine, Infectious Disease Service**

C-86-060 Dooley DP	T	Natural History of HTLV-III Infection and Disease in a United States Military Population .....	240
C-87-052 Myhand RC	O	Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma, Using Ex-Vivo Marrow Treatment with 4-Hydroperoxycyclophosphamide (4-HC) .....	241
C-91-014 Davis C	C	Active Immuniation of early HIV Infected Patients with Recombinant GP160 HIV Protein: Phase II Study of Toxicity Immunotherapy, In Vivo Immunoregulation and Clinical Efficacy .....	242
C-92-018 Dooley DP	O	The Natural History of HIV Infection and Disease in US Military Beneficiaries .....	243
C-92-053 Dooley DP	O	Core Protocol for IV Developmental Diagnostic (Adults) .....	244
C-93-018 Dooley DP	O	Monokine Induction in Patients Infected with Coccidioides Immitis .....	245
C-93-049 Dooley DP	O	Monokine Production in Patients Co-Infected with Mycobacterium Tuberculosis and the Human Immunodeficiency Virus .....	246

<b><u># and PI</u></b>	<b><u>Status</u></b>	<b><u>Title</u></b>	<b><u>Page</u></b>
C-94-088 Dooley DP	O	A Blinded, Randomized Trial Comparing Zidovudine (ACV) vs ZDV + Didanosine (dI) vs ZDV + ddI + Nevirapine in Asymptomatic Patients on ADV Monotherapy Who develop a Mutation at Codon 215 of HIV Reverse Transcriptase in Serum/Plasma Viral RNA .....	247
C-94-089 McAllister K	O	A Randomized, Controlled, Multicenter Trial of Filgrastim (Recombinant-Methionyl Human Granulocyte Colony Stimulating Factor) for the Prevention of Grade 4 Neutropenia in Patients with HIV Infection .....	248
C-95-022 Dooley DP	T	A Randomized, Multicenter, Investigator-Blind Trial Comparing Intravenous CP-116,517 Followed by Oral CP-99,219 with Intravenous Ciprofloxacin and Ampicillin followed by Oral Ciprofloxacin and Amoxicillin for the Treatment of Community Acquired Pneumonia .....	249
C-96-128 Dooley DP	O	DdI Single Dose vs Twice Daily Dosing with and without Hydroxyurea Using the DdI Pediatric Suspension Powder in HIV Positive Individuals .....	250
C-96-138 Coble P	O	Evaluation of the Effect of combination Azithromycin and Fluconazole on the QT Interval in Both Healthy and HIV Infected Subjects .....	251
C-96-147 Dooley DP	O	The Effect of Moving to a New Hospital Facility on the Prevalence of Endemic Resistant Nosocomial Pathogens .....	252

### **Department of Medicine, Nephrology Service**

C-90-040 Wortham W	O	Prostaglandin Excretion of Radiocontrast Induced Acute Renal Failure .....	253
C-92-068 Seiken GL	T	Prophylactic Low Dose Coumadin and Antiplatelet Therapy in the Nephrotic Syndrome Secondary to Membranous Nephropathy .....	254
C-93-024 Abbott KC	O	Comparison of the Effects of Nifedipine and Isradipine on Urinary Albumin Excretion and Blood Pressure in Patients with Type Two Diabetes, Hypertension and Proteinuria .....	255
C-96-033 Abott KC	O	Non-linear Time Series Analysis of Dialytic Arterial and Venous Pressures to Forecast Vascular Access Thrombosis .....	256

### **Department of Medicine, Pulmonary Disease Service**

C-90-024 Anders GT	T	Induction of TNF $\alpha$ and IL-1 in Human Tuberculosis .....	257
C-91-011 Johnson J	O	The Effect of Oxygen Breathing Upon Lung Machines in Patients with Emphysema .....	258

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-91-028 Honeycutt WT	T	Exercise Induced Oxyhemoglobin Desaturation as a Predictor of Nocturnal Desaturation in Chronic Obstructive Pulmonary Disease Patients .....	259
C-93-102 Morris MJ	O	The Risk of Hemorrhage in Patients with Interstitial Lung Disease Undergoing Transbronchial Lung Biopsy: An Analysis of Pulmonary Hypertension as a Risk Factor .....	260
C-94-034 Anders GT	O	Comparison of Fluorescent Bronchoscopy to White-Light Bronchoscopy in Detecting Lung Carcinoma .....	261
C-94-105 Atkins J	O	The Use of Albuterol in the Premedication of Patients with Chronic Obstructive Pulmonary Disease Undergoing Routine Flexible Fiberoptic Bronchoscopy .....	262
C-94-110 Bradley JP	C	A Prospective Randomized Double-Blind Study Comparison of Flexible Fiberoptic Bronchoscopy with and without Use of Preprocedure Sedation .....	263
C-95-139 Ouellette DR	O	Do Alveolar Macrophages from Emphysematous Patients Produce Increased Levels of Proteases? .....	264
C-96-059	O	Comparison of Selected Criteria for Differentiating Pleural Effusion Exudates from Transudates .....	265
C-96-062 Morris MJ	O	Evaluation of exertional Dyspnea in the Active Duty Patient: An Analysis of Dyspnea Symptoms and the Utility of Clinical Testing .....	266
C-96-066 Worley BD	O	Prevalence of Obstructive Sleep Apnea in Patients with Severe Gastroesophageal Reflux Disease .....	267
C-96-092 Morris MJ	O	Comparison of the Work of Breathing Between CPAP and Flow-by Triggering During Weaning from Mechanical Ventilation .....	268
C-96-125 Johnson JE	O	The Acute and Chronic Effects of Heliox and BIPAP on Exercise Tolerance in Patients with Chronic Obstructive Pulmonary Disease .....	269
C-96-126 Ouellette DR	O	Reduction Pneumoplasty for the Treatment of Emphysema .....	270

## **Department of Medicine, Rheumatology Service**

C-96-032 Swank JT	O	Effects of Salsalate, a Non-acetylated Salicylate, on Bleeding Time and Platelet Function in Patients with Osteoarthritis .....	271
----------------------	---	---	-----



<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
<b>Department of Nursing</b>			
C-94-014 Odom JD	C	Computer Simulation Modeling Applied to Capacity Management Decision Making in a Pediatric Ambulatory Clinic .....	272
C-95-003 Wanersdorfer E	C	Evaluation of a Structured Physical Fitness Program for Pregnant Soldiers: Effects on Weight Gain, Blood Pressure, Lost Duty Time, Length of Labor, Infant Birth Weight, and Score on the First Army Physical Fitness Test (APFT) Post Delivery .....	273
C-95-014 Reilly M	C	Alternative Pain Therapy & Anxiolysis in Surgery .....	274
C-95-035 Chandler PE	C	Identification of Family Strengths and Needs Using the Q-sort Process .....	275
C-95-040 Yoder LH	O	An Exploration of Quality of Life Experienced by People with Cancer .....	276
C-95-041 Chandler P	T	A Comparative Study of Parental Stress in the Neonatal Intensive Care Unit .....	277
C-95-042 Hodge NS	O	Determinants of Health-Promoting Behaviors of Patients with Chronic Stable Angina .....	278
C-95-077 Cobb GA	O	Pressure Ulcers: Patient Outcomes on a Kinair Bed or EHOB Mattress .....	279
C-95-078 Anderson SE	O	An Exploration of Quality of Life Experienced by People with Chronic Obstructive Pulmonary Disease .....	280
C-95-079 Noble LJ	T	A Comparison of Two Totally Implanted Venous Access Devices .....	281
C-95-080 Bauch TD	T	Coronary Blood Flow Hemodynamics in Patients with Left Bundle Branch Block .....	282
C-95-081 Hodge NS	O	An Exploration of Quality of Life Experienced by People with Congestive Heart Failure .....	283
C-95-121 Bequette B	O	Comparison of the Relationship Between Patient Height vs the Vertebral Column Length and the Level of Subarachnoid Sensory Blockade Produced Using 0.75% Bupivacaine .....	284

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-95-129 Yoder LH	O	Fatigue Experienced by Bone Marrow Transplant Patients: An Exploratory Study .....	285
C-95-131 Blanke JA	W	Outcomes Management: A Mechanism for Predicting Post-Operative Wound Infections .....	286
C-95-134 Foley B	O	Staged-Based Smoking Cessation Project .....	287
C-96-013 Yoder LH	O	Functional Status and Quality of Life Experienced by Women with Breast Cancer .....	288
C-96-044 Altenburg S	C	After Effects of Perineal Injury Sustained During Childbirth .....	289
C-96-069 Suentzenich B	C	The Effects of Information Provided in a Pulmonary Rehabilitation Booklet on Improving the Pulmonary and General Functional Status of Adult Patients with Chronic Obstructive Pulmonary Disease .....	290
C-96-099 Nichols VJ	O	Postoperative Oxygen Desaturation Following Spinal Anesthesia .....	291
C-96-100 Minton A	O	Quality of Life Experienced by People with End Stage Renal Failure .....	292
C-96-123 Powers JM	O	Drawing Coagulation Studies from a Normal Saline Venous Access Device in Heparinized Patients .....	293

## **Department of Obstetrics-Gynecology**

C-93-082 Phelps JY	C	Simulation of Cervical Diameter Measurements: An Appraisal of Accuracy .....	294
C-94-030 Higby K	O	Comparison of Anti-Hypertensive Agents for Hypertensive Emergencies in Pregnancy: A Pilot Study .....	295
C-94-045 Marconi M	C	Timing the Postcoital Test: Use of a Home Urinary LH Test vs Traditional Methods .....	296
C-94-050 McCoy CE	O	The Effect of Subcutaneous Terbutaline Therapy on Glucose Tolerance in Pregnancy as Assessed by a Modified Bergman's Minimal Model .....	297
C-94-092 Thornton S	T	Sterilization Regret in a Military Population .....	298

<b><u># and PI</u></b>	<b><u>Status</u></b>	<b><u>Title</u></b>	<b><u>Page</u></b>
C-95-047 Anderson J	T	Influence of Parenteral Progesterone Administration on the Prevalence and Severity of Mastodynia in Active Duty Service Women . . . . .	299
C-95-132 Heim BK	O	Pertussis Immunity in an Obstetric Population . . . . .	300
C-96-018 Ventura-Braswell A	O	An Evaluation of Pain Perception and Clinical Outcome in Patients Undergoing Amniocentesis with and without Local Anesthesia . . . . .	301
C-96-034 Roell S	O	Does Intraoperative Infiltration with Local Anesthesia Decrease Postoperative Pain? . . . . .	302
C-96-036 Whitcomb BP	O	Evaluation of Self-Monitored Blood Glucose Levels in Post-Partum Class A-2 Gestational Diabetics . . . . .	303
C-96-037 Higby K	O	An Evaluation of the Coagulation Profile in Pregnant Women Treated with Indomethacin for Preterm Labor . . . . .	304
C-96-038 Hayes E	O	Comparative Assessment of Hypercoagulability in Women with and without gynecologic Malignancies Using Thromboelastography . . . . .	305
C-96-084 Hines J	O	An Evaluation of Antibodies to Human Papillomavirus Types 6, 11, 16 and 18 in Sera and HPV Protein Expression in Tissue of Uninfected and HPV Infected Women: A Pilot Seroepidemiologic Study . . . . .	306
C-96-085 Hines J	O	Evaluation of the Endometrium in Asymptomatic Postmenopausal Breast Cancer Patients Treated with Tamoxifen: A Comparison of Progesterone Challenge Test vs Endometrial Biopsy . . . . .	307
C-96-105 Staten PL	O	The Effect of Auditory Stimulus on Memory . . . . .	308

### **Department of Pathology/Area Laboratory Service**

C-93-013 Fish MH	O	Islet Cell Hyperplasia of the Pancreas in Adults: An Immunohistochemical and Morphometric Study . . . . .	309
C-93-116 Enghardt M	O	Development of a Synthetic Biologic Control for Immunohistochemical Procedures . . . . .	310
C-95-085 Mego TS	C	Organochlorine Exposure and Breast Cancer . . . . .	311
C-95-144 Whelen AC	O	Surveillance of Antibiotic Resistance Among Invasive Strains of Streptococcus Pneumoniae in San Antonio . . . . .	312

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
<b>Department of Pediatrics</b>			
C-87-079 Tiwary CM	C	Appetite and Pectin .....	313
C-90-062 Pick T	O	High Dose Chemotherapy with Autologous bone Marrow Rescue in Children with Recurrent or Progressive Solid Tumors or Primary CNS Malignancies: A Phase II Study (Collaborative Study with Walter Reed Army Medical Center) .....	314
C-92-002 Tiwary C	C	Childhood Obesity: Incidence Density Among Childhood Military Dependents and Association of Obesity with the Duty Status of the Sponsor ...	315
C-93-009 Gomez L	T	Extracellular Fluid Volume Loading and Prevention of Amphotericin B Nephrotoxicity .....	316
C-93-061 Cieslak TJ	T	Low-Volume Blood Culture Sampling in Immunocompromised Children .....	317
C-94-003 Nickels DA	T	Growth and Endocrine Function in Children After Bone Marrow Transplantation .....	318
C-94-006 Cieslak TJ	C	Immunologic Characterization of Coagulase-Negative Staphylococci .....	319
C-94-017 Glasow P	T	Electrocardiographic Voltage Criteria are too Sensitive for Left Ventricular Hypertrophy in Children .....	320
C-94-067 Cieslak TJ	T	Multicenter Double-Blind, Study of Fluconazole in the Early Empirical Treatment of Suspected Fungal Infections in Febrile Neutropenic Patients Undergoing Therapy for Cancer .....	321
C-94-101 Tiwary C	O	Effect of Exercise on Blood Glucose Level Among Children with Insulin Dependent Diabetes Mellitus (IDDM) .....	322
C-94-124 Inscore SC	O	Epidemiologic Study of Cystic Fibrosis .....	323
C-94-140 Inscore SC	C	A Six Month Randomized, Parallel Group, Double-Blind Clinical Trial Comparing Amiloride Hydrochloride with Placebo in Adolescent and Adults with Cystic Fibrosis .....	324
C-95-043 Sanford C	T	Impact of Endotracheal Suctioning with Zero End Expiratory Pressure (ZEEP) vs Positive End Expiratory Pressure (PEEP) on Physiology of Premies .	325

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-95-091 George S	C	Effect of Storage Method on Urine pH Over Time .....	326
C-95-098 Tiwary C	O	The Prevalence of Premature Sexual Development in Children Attending the Pediatric Clinics .....	327
C-95-135 Schmidt HJ	C	A Phase III Placebo Controlled Clinical Trial (PC-TNDS-002) to Study the Study the Efficacy of Tobramycin for Inhalation in Patients with Cystic Fibrosis .....	328
C-96-060 Schmidt HJ	O	An Open Label Follow On Trial of Tobramycin Solution for Inhalation in Patients with Cystic Fibrosis (CF)(PC-TNDS-004) .....	329

### **Physical Medicine/Rehabilitation Service**

C-93-016 Deyle G	T	Comparison of four Treatment Approaches for Adhesive Capsulitis of the Shoulder .....	330
C-93-138 Cowsar JD	T	Use of An Anti-Spasmodic Medication (Dicyclomine) Prior to Flexible Sigmoidoscopy .....	331
C-94-107 Shaffer S	O	The Compariative Effectiveness of Standard Care, Ultrasound and Phono- phoresis with Fluocinonide Gel for the Treatment of Patellar Tendinitis .....	332
C-94-113 Deyle G	O	A Comparison of Two Physical Therapy Treatment Approaches to Shoulder Impingement: Rotator Cuff Exercise Program and Rotator Cuff Exercise with Manual Physical Therapy .....	333
C-94-132 Freund JE	O	Normative Data for the Timed Functional Movements Test .....	334
C-95-033 Underwood F	T	Validation of a Modified Surface Electrode for Sensory Nerve Conduction Testing .....	335
C-95-102 Campbell SM	C	Effects of Hazardous Chemical Protective Equipment on Static Balance .....	336
C-95-103 Childs JD	C	The Effect of Repeated Bouts of Backward Walking at a Constant Workload on Metabolic Efficiency .....	337
C-95-105 Majkowski GR	C	The Effect of Back Belt Use on Isometric Lifting Force and Fatigue of Lumbar Paraspinal Muscles .....	338
C-95-107 Newman D	C	Measures of Balance in Patients Following Total Hip Arthroplasty .....	339

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-96-040 Underwood F	O	Effect of Semi-rigid Lumbosaral Orthosis Use on Oxygen Consumption During Lifting .....	340
C-96-041 Underwood F	O	Effect of Stimulator Position on F-wave Latency .....	341
C-96-042 Wright D	O	Response Stability of Balance Measures Using the Neuro-Com Smart Balance Master .....	342
C-96-047 Underwood F	O	Prediction of 10-Repetition Maximum (10-RM) Based on Hand-Held Dynamometer Force Values .....	343
C-96-048 Underwood F	O	Changes in Hip Extension Range of Motion Following Hip Flexor Stretching or Hip Extensor Strengthening .....	344
C-96-049 Underwood F	O	Quadriceps Femoris and Gluteus Maximus Activity during Stair Climbing .....	345
C-96-070 Henderson NE	O	Training Injuries in Advanced Individual Training: An Exploratory Study .....	346

## **Department of Psychiatry**

C-96-006 Orman D	O	Psychophysiology of a Neuroleptic 'Therapeutic Window' .....	347
---------------------	---	--	-----

## **Department of Radiology**

C-77-012 Sostre G	T	Intravenous Administration of I131 (NP 59) for Adrenal Evaluation of Imaging .....	348
C-89-047 Heironimus JD	T	Evaluation of 131I-miBG (131I-meta-iodobenzylguanidine sulfate) in Patients Suspected of Having Pheochromocytoma, Paraganglioma or Medullary Hyperplasia .....	349
C-94-047 Sostre G	T	A Prospective Evaluation of Technetium 99m Sestamibi in The Detection of Breast Cancer .....	350
C-95-044 Sostre G	O	A Randomized, Double-Blind, Placebo Controlled Study of the Effect of Cilostazol on Gastric Emptying in Patients with Intermittent Claudication Secondary to Peripheral Vascular Disease .....	351
C-95-089 Washowich T	O	Ureteral Jets in Normal Pregnancy .....	352

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-96-002 Chacko AR	O	Film-Screen and Direct Digital Mammography: A Comparison of Radiologic Interpretation and Clinical Management Recommendations .....	353
C-96-016 Burke B	O	A Comparison of Power and Conventional Color Doppler Sonography in the Detection of Intratesticular Blood Flow in Prepubertal Males .....	354
C-96-021 McBiles M	O	Study of Intravenously Administered 111-In Capromab Pentetide in Evaluation of Patients with Prostate Cancer .....	355
C-96-068 Boyle ER	O	Digital Mammography: Preliminary Demonstration of Clinical Feasibility .....	356
C-96-077 Glenn E	O	DoD Screening for Breast Cancer: Where Have All the Women Gone? .....	357
C-96-097 Trainor PJ	O	Selective Salpingography and Fallopian Tube Recanalization - The Brooke Army Medical Center Experience .....	358
C-96-112 McBiles M	O	Simultaneous Transmission/Emission Protocol (STEP) for Attenuation Correction of Breast and Diaphragmatic Attenuation Artifacts During SPECT 99mTc-Sestamibi Myocardial Perfusion Scans in Women Without Coronary Artery Disease .....	359
C-96-137e Stoffey RD	O	Pediatric Subarachnoid Hemorrhage in Patients with a Cryptic CNS Vascular Malformation, a Case Report and Current Literature Review .....	360

### **Department of Surgery, Anesthesiology/Operative Service**

C-91-050 Schiffer D	O	Comparison of Trigger Point Injections Using Kerolac Tromethamine vs Saline in the Treatment of Myofascial Pain Syndrome .....	361
C-91-073 Mongan PD	C	Does Magnesium Decrease the Incidence and Severity of Post-Cardiopulmonary Bypass Arrhythmias: A Double Blind, Randomized, Placebo Controlled Clinical Trial .....	362
C-91-093 Mongan PD	T	Aeric and Particulate Microemboli as Etiologic Factors in the Development of Neurobehavioral Dysfunction Following Cardiopulmonary Bypass and Vascular Surgery: An Outcome Study .....	363
C-92-026 Mongan PD	O	Determination of Vecuronium Bromide Requirements in Nonthermally Injured Patients .....	364
C-93-068 Szigeti C	T	A Study of Intra-incisional Bupivacaine and Intramuscular Ketorolac for Postoperative Pain Relief Laparoscopic Bilateral Tubal Electrofulguration .....	365

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-93-078 Anderson DM	O	The Use of EEG and Hemodynamic Parameters in the Design of Intelligent Anesthetic Control Systems .....	366
C-93-113 Mongan PD	C	Effects of Desflurane on the Amplitude and Latency Characteristics of Brainstem Auditory, Midlatency Auditory, Median and Posterior Tibial Nerve Evoked Potent .....	367
C-94-001 Szigeti C	C	Magnitude of Hypotension with and without Intravenous Fluid Preload in Healthy Patients Receiving Subarachnoid Anesthesia .....	368
C-94-005 Anderson D	T	Oral Atropine Premedication in Children: Effects on Airway and Respiratory Events During General Anesthesia for PE Tube Placement .....	369
C-94-018 Storch TD	O	Determination of Perioperative Intravascular Volume Status in TURP Patients Under Subarachnoid Anesthesia .....	370
C-94-021 Sayson SC	O	A Prospective Study Evaluating Optimal Volume of Blood Injected into the Epidural Space for treatment of Post Dural Puncture Headache .....	371
C-94-031 Szigeti C	T	Headache After Spinal Anesthesia for Cesarean Section: A Comparison of the Quincke and Whitacre Spinal Needles and the Paramedian and Midline Approaches .....	372
C-94-033 Brown RS	C	The Effect of Transexamic Acid when Given After Cardiopulmonary Bypass and Its Correlation with Thromboelastography .....	373
C-94-046 Szigeti C	T	A Study of the Ability of Anesthesiologists and Surgeons to Differentiate Arterial from Central Venous Blood Samples by Visual Inspection of Hue .....	374
C-94-052 Brown RS	O	Incident of Post-dural Puncture Headaches with Continuous Spinal Anesthesia and 24-Gauge Catheter Over 26 Gauge Needle .....	375
C-94-062 Thwaites BK	C	The Effect of Intravenous Ketorolac on Platelet Function During General Anesthesia .....	376
C-94-073 Chronister TL	T	Sore Throat with the Laryngeal Mask Airway in Pediatric Patients - The Effect of Lubrication .....	377
C-94-074 Chronister TL	T	Sore Throat with the Laryngeal Mask Airway - The Effect of Lubrication .....	378
C-94-076 Mongan P	T	Rocuronium Onset of Action: An EMG Dose Response Study of the Adductor Pollicis, Orbicularis Oculi and the Adductor Muscles of the Larynx .....	379



<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
C-94-097 Chronister TL	T	Postoperative Nausea & Vomiting in Females Based on Menstrual History - Effect of Various Prophylactic Antiemetic Regimes .....	380
C-94-108 Chronister TL	O	Survey of Current Opinion on the Diagnosis and Treatment of Suspected Intraoperative Malignant Hyperthermia .....	381
C-94-115 Swide CE	T	A Study of Headache After Spinal Anesthesia for Cesarean Section: A Comparison of the Quincke and Whitacre Spinal Needles and the Pramedian and Midline Approaches .....	382
C-95-010 Mongan PD	C	A Pilot Study of the Pharmacokinetics and Pharmacodynamics of Etomidate Administered by Inhalation .....	383
C-95-011 Vories PA	C	Effect of Nebulized Tetracaine on the Hemodynamic Response to Laryngoscopy and Tracheal Intubation .....	384
C-95-015 Mongan PD	O	A Comparison of Aprotinin and Tranexamic Acid in Reducing Mediastinal Chest Tube Drainage and Allogenic Transfusions After Cardiopulmonary Bypass .....	385
C-95-072 Stevens JB	T	Use of a Priming Dose of Vecuronium Prior to Rocuronium for Rapid Sequence Induction of Anesthesia .....	386
C-95-083 Chronister TL	O	Determination of Normal Thromboelastogram (TEG) Parameters in Healthy Pregnant Women at Various Gestational Ages .....	387
C-95-092 Cheung C	O	The Effect of Epidural Volume on the Spread of Dermatomal Analgesia with Subarachnoid Hyperbaric Bupivacaine .....	388
C-95-119 Oldroyd R	W	A Direct Comparison of two Methods for Determining Cardiac Output and Pulmonary Artery Pressure in the Operating Room: Transesophageal Echocardiography and Pulmonary Artery Catheterization ....	389
C-95-137 Storch TD	O	Subanesthetic Propofol Infusion for Prophylaxis Against Emesis in Laparoscopic Day Surgery .....	390
C-95-138 Jones PE	O	A comparison of Prophylactic Ondansetron and Droperidol for Strabismus Repair in Adults .....	391
C-95-142 Stevens JR	O	Hemodynamic Effects of Rocuronium Compared to Vecuronium .....	392
C-96-039 Stevens JR	O	Tracheal Intubation without Muscle Relaxant: Alfentanil with Triopental, Propofol or Etomidate with or without Lidocaine .....	393

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-96-093 Stevens JR	O	Cisatracurium Neuromuscular Blockade: Speed of Onset Using the Priming Principle and Antagonism with Neostigmine .....	394
C-96-106e Walker S	O	Pulse Oximetry Factor Structure in Euvolemic vs Hypovolemic Patients .....	395
C-96-107e Walker S	O	Aerobic Cultures of Disposable Anesthesia Circuit Systems: A Study of Reuse Safety .....	396
C-96-110 Smagula CM	O	Consideration of Cervical Dilation and Parity when Choosing Between Intrathecal and Epidural Analgesia for Labor .....	397

### **Department of Surgery, Cardiothoracic Surgery Service**

C-93-048 Cohen DJ	T	Clinical Evaluation of Left Ventricular Assist Device .....	398
C-94-028 Bowman G	T	Clinical Evaluation of Low Dose Heparin in Conjunction with a Heparin Coated Circuit for Cardiopulmonary Bypass .....	399

### **Department of Surgery, General Surgery Service**

C-91-092 Robertson FM	T	Does Preoperative Axillary Ultrasound and Tumor DNA Content Predict Axillary Lymph Node Metastases in Breast Cancer Patients with Clinically Negative Axilla .....	400
C-93-120 Alvarez J	O	Menstrual Cycle Impact Upon Breast Cancer - Woman - Surgery Balance .....	401
C-94-061 Kelemen JJ	O	Peritoneal Irrigation in Gunshot Wounds of the Abdomen .....	402
C-95-109 Jatoi I	O	Biomarkers as Surrogate Endpoints in a Pilot Breast Cancer Chemoprevention Trial Using Tamoxifen .....	403
C-96-014 Fengler SA	W	A Randomized, Dbl-Blind, Multicenter Trial Assessing the Safety and Efficacy of a single Intravenous Dose of CP-116,517 Compared with Cefotetan for the Prophylaxis of Infection Following Elective Colo-rectal Surgery .....	404
C-96-061 Kelemen JJ	O	General Surgery Selective Management of Stable Patients with Suspected Tangential Gunshot Wounds to the Abdomen .....	405
C-96-073 Jatoi I	O	Bone Marrow Micrometastases in Premenopausal Breast Cancer: Relevance to Timing of Surgery .....	406

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
<b>Department of Surgery, Ophthalmology Service</b>			
C-88-079 Holck D	O	Collaborative Ocular Melanoma Study (COMS) .....	407
C-94-041 O'Hara M	C	Efficacy and Safety of Ciprofloxacin Ophthalmic Ointment vs TOBREX Ophthalmic Ointment for Treating Bacterial Conjunctivitis in Children .....	408
C-95-018 Bauman WC	O	Intraocular Silicone Oil in Surgery for Otherwise Inoperable Retinal Detachment .....	409
C-95-116 Campagna JA	O	Intraocular Pressure Response to Nasal Steroids .....	410
C-95-133 Leuschner EF	C	A Research Study to Determine the Effect of Punctal Occlusion on Intraocular Pressure in Patients Taking Topical Glaucoma Therapy .....	411
C-96-003 Bauman WC	O	A Prospective, Randomized Clinical Trial Comparing Topical Prednisolone 1% to Diclofenac 0.1% in the Treatment of Pseudo- phakic Cystoid Macular Edema (PCME) .....	412
C-96-029 Dunlap WA	C	A Prospective Multicenter Non-Randomized Clinical Study to Evaluate Viteron as an Intraoperative Surgical Aid in the Giant Retinal Tear Patients ...	413
C-96-135	O	Determination of Prevalence of Clinical and Subclinical Kera- toconus in Patients with Mitral Valve Prolapse .....	414

### **Department of Surgery, Orthopedic Surgery Service**

C-92-035 Stannard JP	C	Use of a Foot Compression Pump in the Prevention of Deep Vein Thrombosis in Hip Fractures .....	415
C-94-009 Dahl JA	T	The Incidence of Concomitant Leg and Foot Compartment Syndrome .....	416
C-94-081 Wilkey KD	C	Mechanical Characteristics of the Femoral Intramedullary Nailing Systems Available from Five Different Manufacturers .....	417
C-96-011 Wahlgren V	O	Vascular and Gross Anatomy of the Patellar Tendon .....	418
C-96-015 Komas N	C	Flexor Tendon Repair: The Analysis of the Bulk of Repair Measured as Resistance to Gliding .....	419

<b><u># and PI</u></b>	<b><u>Status</u></b>	<b><u>Title</u></b>	<b><u>Page</u></b>
C-96-035 Stannard JP	O	Use of Intermittent Plantar Compression to Treat Swelling Associated with Calcaneal Fractures .....	420
C-96-046 Wahlgren V	O	A Comparative Trial of 2-Octyl Cyanoacrylate for the Approximation of Incised or Lacerated Skin .....	421
C-96-054 Baumann RL	O	Comparison of Three vs Four Cortical Fixation of the Injured Distal Tibiofibular Syndesmosis in Cadavers .....	422

### **Department of Surgery, Otolaryngology Service**

C-91-076 Esquivell C	O	Efficacy of Steroids in Reducing Post-Tonsillectomy Morbidity .....	423
C-93-032 Otto RJ	T	Evaluation of Gastroesophageal Reflux in Preterm Infants .....	424
C-93-051 Ramirez SG	O	Mandibular Reconstruction by Distraction Osteogenesis .....	425
C-95-045 Ramirez SG	O	The M-40A1 Protective Masks' Effect on Sleep: A Preliminary Study .....	426
C-95-068 Balbuena L	O	The Effect of a Peridex Rinsing Regimen on Wound Infection Rates in Major Head and Neck Surgery .....	427
C-95-070 Lee JJ	C	Racial Variations in Cephalometric Analysis .....	428

### **Department of Surgery, Urology Service**

C-90-091 Thompson IM	C	Phase I Protocol for the Evaluation of Active Immunization Against LHRH in Patients with Metastatic Cancer of the Prostate .....	429
C-91-074 Thompson IM	O	Randomized Prospective Study Comparing Radical Prostatectomy Alone vs Radical Rostatectomy Preceeded by Androgen Blockade in Clinical B2 Prostate Cancer .....	430
C-92-057 Thompson IM	O	Prostatic Intraepithelial Neoplasia as a Predictor of Subsequent Development of Carcinoma of the Prostate .....	431
C-93-023 Thompson IM	O	Phase III Trial of Coumarin (1,2-Benzopyrone) in Patients with Clinically Localized Prostatic Carcinoma Treated by Radical Prostatectomy found Pathologically to have High Risk of Recurrence .....	432

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
C-94-078 Thompson IM	O	Survival and Morbidity Tradeoffs in Prostate Cancer Treatment - Impact of Patient Perspective .....	433
C-94-093 Thompson IM	T	A Phase II Study: Intravesical N-Trifluoroacetyladiamycin-14- Valerate (AD 32) in Patients with Cell Carcinoma in situ of the Bladder Who Have Failed or Have Recurrence Following Treat- ment with Bacillus Ccalmette-Guerin .....	434
C-94-094 Thompson IM	T	A Phase II Study: Intravesical N-Trifluoroacetyladiamycin-14- Valerate (AD 32) in Patients with Transitional Cell Carcinoma of the Bladder .....	435
C-94-133 Cornum R	W	Effects of Breast Cancer on Prostate Cancer Risk .....	436
C-95-012 Thompson IM	O	Use of Alpha-Adrenergic Blocking Agents Compared to Anti- Cholinergic Agents and Placebo in Women with Obstructive/ Irritative Voiding Symptoms .....	437
C-95-082 Foley JP	O	A Clinical Trial of Medical Therapy in Benign Prostatic Hyperplasia .....	438
C-95-087 Thompson IM	C	Sampling Error in Posttherapy Prostate Biopsy .....	439
C-95-123 Rozanski T	O	Comparative Study of the Clinical Efficacy of Two Dosing Regimens of EULEXIN .....	440
C-95-140 Schow D	O	Results of Transurethral Incision/Resection of the Prostate in Men Treated Medically for Benign Prostatic Hyperplasia .....	441
C-96-001 Foley JP	O	Creation of a Prostate Cancer Data Base .....	442
C-96-002 Thompson IM	O	Pilot Study: Linkage Analysis of Prostate Cancer Families .....	443
C-96-017 Friedrichs P	O	Center for Prostate Disease Research (CPDR) Prostate Cancer Radical Prostatectomy Follow-Up Questionnaire .....	444
C-96-094 MacIsaac SG	O	A Phase II Study to Determine the Effect of Finasteride & Flutaide on Patients with Rising PSA's Who have had Radical Prostatectomy, Radiation, or Cryoablation Treatment for Localized, Primary Prostate Cancer .....	445

<u># and PI</u>	<u>Status</u>	<u>Title</u>	<u>Page</u>
<b>Department of Social Work</b>			
Pending Newborn J		Spouse Abuse Among Active Duty Women Married to Civilian Husbands: An Examination of Interpersonal and Social Factors .....	446

## **Darnall Army Community Hospital, Fort Hood, TX**

C-92-007 Ferrara A	T	Comparison of Cimetidine, Ranitidine, and Diphenhydramine in the Treatment of acute Urticaria Over a Seventy-two Hour Period .....	447
C-93-002 Wroblewski CS	T	Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas .....	448
C-93-128 Hammond K	C	A Prospective Randomized Double-Blinded Evaluation of Prochlorperazine vs Sumatriptan for the ED Treatment of Migraine Headache .....	449
C-94-040 Foster MS	T	Efficacy and Safety of Ciprofloxacin Ophthalmic Ointment vs TOBREX Ophthalmic Ointment for Treating Bacterial Conjunctivitis in Children .....	450
C-94-058 Ching DT	O	A Double Blind Evaluation of Ketorolac Tromethamine and Butorphanol Tartrate for the Emergency Department Management of Ureteral Colic .....	451
C-94-098 Coppola M	T	A Double-Blinded, Randomized Comparison of Viscous Lidocaine Gel for Topical Anesthesia of Dermal Lacerations in Adults .....	452
C-94-102 Garra more JA	C	A Radiographic and Functional Analysis of Short Arm Cast vs Volar Splint Immobilization in Preventing Angulation of Small Finger Metacarpal Neck Fractures .....	453
C-94-128 Melendez L	O	Relationships of Smoking Behavior, Health Beliefs, and Health Values Intentions to Smoke among Pregnant Women in a Military Health Care Setting .....	454
C-94-141 Coppola M	O	Analgesia for reduction of Acute Glenohumeral Dislocation: Intra-articular Lidocaine Versus Intravenous Fentanyl .....	455
C-95-003 Wanersdorfer E	C	Evaluation of a Structured Physical Fitness Program for Pregnant Soldiers: Effects on Weight Gain, Blood Pressure, Lost Duty Time, Length of Labor, Infant Birth Weight, and Score on the First Army Physical Fitness Test (APFT) Post Delivery .....	456

<b># and PI</b>	<b>Status</b>	<b>Title</b>	<b>Page</b>
C-95-006 Coppola M	O	The Efficacy of Nebulized Dexamethasone in the Treatment of Acute Asthma .....	457
C-95-032 Vikram PZ	O	Tamoxifen as Treatment for Idiopathic Gynecomastia .....	458
C-95-034 Smith D	O	Comparison of Outpatient Treatments for Pyelonephritis .....	459

### **Evans Army Community Hospital, Fort Carson CO**

C-96-096 Davis D	O	Neurogenic Hypotension in Gulf War Veterans with Chronic Fatigue .....	460
---------------------	---	--	-----

### **Irwin Army Community Hospital, Fort Riley, KS**

C-96-108 McGovern TW	O	A Randomized Double-Blind, Placebo Controlled Efficacy and Safety Study of Oral Lobucavir in Patients with Recurrent Genital Herpes .....	461
C-96-109 McGovern TW	O	A Randomized Double-Blind, Placebo controlled Efficacy and Safety Study of Oral Lobucavir in Patients with Recurrent Herpes Labialis .....	462
C-96-120 Remund D	O	Epidemiology of Prescribed Medication Use Among Active-Duty Troops, Retired Soldiers and Their Families .....	463

### **Leonard Wood Army Community Hospital, Fort Leonard Wood, MO**

C-96-144 Kimmel DB	O	A Prospective Study of the Risk of Stress Fracture in Male Army Recruits During Basic Training .....	464
-----------------------	---	--	-----

### **Dugway Proving Grounds, UT**

C-96-113 Laraway JD	O	Evaluation of a Phase I Coxiella Burnetii Vaccine (IND 610) for Immunization Against Q Fever .....	465
C-96-114 Larawan JD	O	Continued Eval of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, TC-83 Live, Attenuated, NDBR-102, Lot 4 in At-Risk Personnel IND 142 .....	466
C-96-115 Laraway JD	O	Evaluation of New Lots of Tularemia Vaccine, Protocol B: Comparative Assessment of Francisella Tularensis Vaccine, Live, NDBR 101, IND 157 .....	467

<b><u># and PI</u></b>	<b><u>Status</u></b>	<b><u>Title</u></b>	<b><u>Page</u></b>
C-96-116 Laraway JD	O	Evaluation of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated Protocol B: Contd Assessment of the Safety & Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Lot C-84-6, TSI-GSD 205 as a Booster in At-Risk Personnel IND 914 .....	468
C-96-117 Laraway JD	O	Administration of Equine Heptavalent Antitoxin for Therapy of Suspected Botulism Intoxication .....	469
C-96-118 Laraway JD	O	Inoculation with Pentavalent (ABCDE) Botulinum Toxoid (CDC IND #161) .....	470

### **Fitzsimons Garrison, Aurora CO**

C-96-063 McDermott	O	Assessment of Dietary Calcium Intake, Physical Activity and Habits Affecting Skeletal Health Among Premenopausal Military Women .....	471
C-96-121 Supon P	O	BioStar Optical Immunoassay for Detection of Group A Streptococcus Directly from Pharyngeal Specimens .....	472
C-96-122 Titze M	O	Hypertension Optimal Treatment International Study .....	473

### **US Southern Command, NAMRID Lima Peru**

C-96-140 Taylor DN	O	Expanded Safety and Immunogenicity of a Bivalent Oral Attenuated Cholera Vaccine, CVD 103-HgR + CVD111 in Healthy US Adult Volunteers .....	474
-----------------------	---	---	-----



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**FISCAL YEAR 1996**

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PU    **Grady, EP; Carpenter, MT; Battafarano, DF; Older, SA; Koenig, CD**

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PR    **West, SG; Hugler, R; Battafarano, D; McDermott, MT; McBiles, M**

Low-dose methotrexate (MTX) does not cause osteoporosis in rheumatoid arthritis (RA)  
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**Nursing**      PU    **Yoder, L**

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PU    **Schneider JK, Connelly LM, Martin A**

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Jour of Continuing Education in Nursing 1996;27(5):224-227

PR    **Yoder, L**

Oncology for the critical care nurse  
UTHSC Sch of Nursing Graduate Program

PR    **Hunt D**

The effect of white noise sounds and ambient sounds on the night sleep patterns of CABGS patients  
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PR    **Connelly L**

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**Nursing**      PR    **Connelly L**

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PR    **Yoder L**

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PR    **Yoder LH**

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AB    **Yoder L, Drady V**

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AB    **Chandler P**

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**Nutr Care**      PU    **Fiedl, K; Klicka, M; King, N; Marchietelli, L; Askew, E**

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the US Military Academy

Military Medicine, Vol 160, Oct 95

PU    **King N, Askew EW**

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Marriot BM, ed. Nutritional Needs in Cold & in High-Altitude Environments.  
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PR    **King N**

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Initiative, 17-18 Jun 96

**OB-Gyn**      PU    **Hines, J**

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PU    **DeLosSantos, M; Cimis, Rt; Gordon, S; et. al.**

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- PU**    **Phelps, J; Higby, K; Smyth, MH; Ward, JA; et. al.**  
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- PU**    **Hines, JF; Khalifa, MA; Moore, JL; et. al.**  
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- PU**    **Hines JF, Ghim S-J, Schlegel R, et al**  
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- PR**    **Horton, M**  
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- PR**    **Smyth, M**  
Does epidural anesthesia affect mode of delivery  
OB & Gyn Postgraduate Seminar, 3 Apr 96, San Antonio TX
- PR**    **Hines, JF**  
Self assembly of highly oncogenic IIPV-18 into virus-like particles  
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- AB**    **Hines, J**  
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- AB**    **Smyth, M; Higby, K**  
Does epidural anesthesia affect mode of delivery  
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- Peds**            **AB**    **Cuda SE, Frank S**  
Adolescents assess services six months after initiation of a school based  
clinic  
Natl Assembly on School Based Health Care, Baltimore MD, 27-29 Jun 96
- Phsical**        **AB**    **Henderson, N**  
Lower exremity posture-evoked responses in persons with essential tremor  
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- Phys Med**      **PU**    **Harvey, KD; Barillo, DJ; Hobbs, CL; Mazingo, DW; Fitzpatrick, JC; Cioffi, WG; McManus, AT; Pruitt, BA**  
Computer-assisted evaluation of hand and arm function after thermal injury  
J of Burn Care & Rehabilitation, Vol 17, No 2:2-6
- PU**    **Pla MER, Dillingham TR, Spellman NT, Colon E, Jabbari B**  
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Movement Disorders 1996;11(1):82-86 (with videotape)
- PR**    **Harvey, KD**  
Burn rehabilitation: An OT perspective  
12th Annual PM&R Conference, San Antonio, TX, 4 Mar 96
- Physical**      **PU**    **Franklin, R; Bullock, S; Dettori, J**  
The effects of spinal flexion and extension exercises and their associated  
postures in patients with acute low back pain  
SPINE, Vol 20 #21, 1 Nov 95
- PR**    **Stoneman, P**  
Lumbar stabilization  
Central District of the Texas Physical Therapy Assn, Nov 95
- AB**    **Henderson, N**  
Postural control in essential tremor  
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- AB**    **Henderson, N**  
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- Psy**            **PR**    **Clement, P**  
What is intelligence?  
San Antonio Neuropsychological Society, 1 Mar 96
- Radiology**      **PU**    **Arndt, WF; Truax, AL; Barnett, FM; et. al.**  
MR diagnosis of bone contusions of the knee: Comparison of coronal T2-weighted  
fast spin-echo w/fat saturation and fast spin-echo STIR images w/coventional  
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Amer J of Rad 1996; 166:119-24
- PR**    **Cawthon, M**  
Perspectives on training and soft copy interpretation implementation  
Rad Soc of North America, Chicago IL 27 Nov-1 Dec 95
- PR**    **Mogel, G; Cramer, T; et al**  
Department of the future  
Rad Soc of North America, Chicago IL 27 Nov-1 Dec 95
- PR**    **Cawthon, MA**  
Clinical operations in an electronic department  
96 Planning Design and Construction Conf, 22 Mar 96, San Antonio TX

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**Radiology**      PR    **Cawthon, MA**

PACS to telemedicine

96 Life Sci and Space Med Conf and Exhibit, NASA, 7 Mar 96, Houston TX

PR    **Chacko, AK**

Design and implementation of radiology in the electronic hospital of the future

96 Planning Design and Const Conf, 22 Mar 96, San Antonio TX

**Surg/Anes**      PU    **Mingus, M; Levitan, S; Bradford, C; et. al.**

Surgical patients' attitudes regarding participation in clinical anesthesia research

Anesth Analog 1996;82:332-337

PU    **Lavery, LA; Walker, SD; Harkless, LB; et. al.**

Infected puncture wounds in diabetic and nondiabetic adults

Jour of Clin and Applied Research and Educ

PU    **Mongan, PD; Hinman, JA**

Evaluation of a double-lumen multiorifice catheter for resuscitation of swine from lethal venous air

Anesthesiology 83:1104-1111, 1995

PU    **Hecker, RB; Brownfield, RM; Rubal, BJ**

Bayesian analysis of noninvasive versus oral temperature measurements to determine hypothermia in postoperative patients

So Med J 1996; 89:71-77

PU    **Peter, D; Hecker, R; Rubal B**

Pulse-oximetry vs skin color in the evaluation of patients in the post-anesthetic care unit (PACU)

IARS 70th Clin & Scien Congress, Wash DC, 12 Mar 96

PU    **Davis, ST; Hecker, RB; Brown, RS; Rubal, BJ**

A comparison of thermometry modalities in the post-induction surgical patient

IARS 70th Clin & Scien Congress, Wash DC, 12 Mar 96

PU    **Davis, ST; Hecker, RB**

A comparison of thermometry modalities in the post-induction surgical patient

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PU    **Will MJ, Hecker RB, Wathen PI**

Primary varicella-zoster-induced rhabdomyolysis

So Med Jour 1996;89:915-920

PU    **Stevens JB, Hecker RB, Talbot JC, Walker SC**

The hemodynamic effects of rocuronium compared to vecuronium and pancuronium under balanced anesthesia

Anesthesiology 1996;85:A822

PR    **Mongan, P**

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Blood conservation during cardiopulmonary bypass  
Grand Rounds, Univ of Pennsylvania, Hershey Nov 95

PR    **Hecker, RB; Spence**

Current research on the use of Rocuronium bromide in South Texas  
Anesthesia Practice Group (APG), San Antonio 11 Dec 95

PR    **Hecker, RB; Spence**

A review of rocuronium bromide and current research on its use in South Texas  
Laredo Society of Anesthesiologists, Laredo TX 1 Nov 95

PR    **Hecker, RB; Spence**

Osteopathic manipulative therapy (OMT) in pain management  
Anes Pain Svc Grand Rounds, Univ of TX Health Sci Cen, San Antonio 12 Oct 95

PR    **Hecker, RB; Spence**

A review of rocuronium bromide - a new muscle relaxant for rapid sequence  
intubation  
The Baptist Hosp System, San Antonio TX, 9 Oct 95

PR    **Hecker, RB; Spence**

Management of the difficult airway  
The Baptist Hosp System, San Antonio TX, 9 Oct 95

PR    **Storch, T**

Emergency use of induction agents for rapid sequence intubation  
Joint Svcs Symposium, San Antonio, TX, Mar 96

PR    **Jones, P**

Comparison of Ondansetron/Droperidol for adult stablismas surgery  
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PR    **Peters, D**

Pulse oximetry vs skin color in the post-anesthesia care unit (PACU)  
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Comparison of Ondansetron/Droperidol for adult stablismas surgery  
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AB    **Thwaites, BK; Bouska, G; Nigus, DB; et. al.**

Platelet function during spinal anesthesia and surgery before and after  
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Anesthesiology 83:A785, 1995

AB    **Brown, RS; Thwaites, BK; Mongan, PD; et. al.**

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Anesthesiology 83:A97, 1995

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Hemochon on site coagulation monitor as a predictor of bleeding in  
cardiopulmonary bypass patients

Anesthesiology 83:A96, 1995

**AB**    **Thwaites, BK; Mongan, PD; Brown, RS**

Thromboelastographic evidence of fibrinolysis strongly predicts excess bleeding  
after cardiopulmonary bypass

Anesth Analg 80:4S, SCA126, 1995

**AB**    **Brown, RS; Mongan, PD; Thwaites, BK**

Tranexamic acid decreases fibrinolysis, bleeding and blood transfusions in  
primary CABG

Anesth Analg 80:4S, SCA 18, 1995

**AB**    **Thwaites, BK; Nigus, DB; Bouska, G; Mongan, PD**

Platelet function during spinal anesthesia and surgery before and after  
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Anesth Analg 80:S489, 1995

**AB**    **Fontana JL; McGlothin, TM; Mongan, PD; Bunger, R**

Tachycardia does not reflect profound anemia in a porcine model of normovolemic  
hemodilution

Anesth Analg 80:S131, 1995

**AB**    **Storch, TD; Thwaites, BK**

Determination of perioperative intravascular volume in patients undergoing  
laser versus traditional transurethral prostatic resection

Anesth Analg 1996; 82; S429

**Surg/CTS**      **PU**    **Napoli, PJ**

Primary Aortoenteric fistula from a post-traumatic pseudo aneurysm

Jour of Trauma, 95

**PU**    **Napoli PJ**

Primary aortoenteric fistula from a post-traumatic pseudoaneurysm

J of Trauma, July 1996; 41(1):149-152

**PR**    **Cohen DJ**

Mitral valve repair surgery - Techniques and results

9th USUHS Cardiothoracic Symposium, Bethesda MD, 30 May - 1 Jun 96

**PR**    **Cohen DJ**

Heart transplantation - The US Army experience

9th USUHS Cardiothoracic Symposium, Bethesda MD, 30 May - 1 Jun 96

**PR**    **Lisagor PG**

Pneumectomy: History & techniques & results

UTHSC Thoracic Surgery Grand Rounds, San Antonio TX, Apr 96



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**Surg/CTS**      PR    **Lisagor PG**

Operations other than war

9th USUHS Cardiothoracic Symposium, Bethesda MD, 30 May - 1 Jun 96

PR    **McDonnell, BE**

Anomalous right coronary artery originating from the left sinus of valsalva

9th USUHS Cardiothoracic Symposium, Bethesda MD, 30 May - 1 Jun 96

PR    **Lisagor PG**

Coronary artery anamolies

UTHSC Thoracic Surgery Grand Rounds, San Antonio TX, Feb 96

**Surg/Neurosurg**    PU    **Alexander, J**

Natural history and non-operative management of cervical spondylosis

Principles of Spinal Surgery EDS; 1996 Chap 34:547-558

PR    **Alexander, J**

Advanced techniques in thoracolumbar instrumentation

Congress of Neurology Surgeons Mtg, San Francisco CA, Oct 95

**Surg/Oph**      PU    **Campagna, JA; Munden, PM; Alward, LM**

Tenon's cyst formation after trabeculectomy with mitomycin C

Ophthalmic Surg 1995;26:57-60

PU    **Morris, MJ; Peacock, MD; Johnson, JE; et. al.**

Recurrent bilateral spontaneous pneumothoraces associated with pulmonary  
angiocentric immunoproliferative lesion

Southern Medical Journal 1995;88:771-775.

PU    **O'Hara, MA, et al**

Periocular infection after strabismus surgery

Jour of Ped Oph & Strabismus, 32(1):42-49

PU    **Mitchell, KT; Hollsten, DA; White, W; et. al.**

The autogenous dermis-fat orbital implant in children

In Lennerstrand, G(Ed), Transactions of the Inter Strabismological Assn,  
Boca Raton CRC Press 95

PU    **Metz, T; O'Hara, MA; Bauman, WC**

Pars plana vitrectomy and capsulotomy in pediatric cataract extraction  
w/intraocular lens implantation

In Lennerstrand, G(Ed), Transactions of the Inter Strabismological Assn,  
Boca Raton CRC Press 95

PR    **Campagna, J**

IOP measuring devices

Continuing Education Program for Ophthalmic Medical Personnel, Atlanta GA 1  
Nov 95

PR    **Grimes, S**

Optic nerve sheath decompression

Annual Academy of Ophthalmology Mtg, Atlanta GA 30 Oct 95

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- Surg/Oph**      PR    **Beson, J**  
Anti-glaucoma medications  
Continuing Education Program for Ophthalmic Medical Personnel, Atlanta GA 1  
Nov 95
- PR    **Dunlap, W**  
Macular degeneration  
Ophthalmology Grand Rounds UTHSCSA 6 Oct 95
- PR    **Dunlap, W**  
Macular degeneration  
Continuing Education Program for Ophthalmic Medical Personnel, Atlanta GA 2  
Nov 95
- PR    **Chacko, B**  
Current technique of phacoemulsification and small incision implantation  
Continuing Education Program for Ophthalmic Medical Personnel, Atlanta GA 2  
Nov 95
- PR    **Bauman, W**  
Understanding diabetic retinopathy  
Continuing Education Program for Ophthalmic Medical Personnel, Atlanta GA 29  
Oct 95
- PR    **Lloyd, W**  
Handling of clinical and surgical specimens  
Continuing Education Program for Ophthalmic Medical Personnel, Atlanta GA 29  
Oct 95
- PR    **Lloyd, W**  
Pathology of eyelid tumors  
Oph Conf, Scott & White Clinic, Temple TX 17 Nov 95
- PR    **Lloyd, W**  
Basic mechanisms of ocular disease  
UTHSCSA Dept of Path, San Antonio TX 21 Nov 95
- PR    **Lloyd, W**  
Introduction to ophthalmic pathology  
Ophthalmology Dept, Texas Tech Health Sci Cen, Lubbock TX 8 Dec 95
- PR    **O'Hara, M**  
Help! There's a child in my chair  
Continuing Educ Program for Ophthalmic Medical Personnel, Atlanta GA 30 Oct  
95
- PR    **Bauman, WC**  
Management of subfoveal choroidal neovascularization in patients with ocular  
histoplasmosis and idiopathic subfoveal choroidal neovascularization  
Everett R. Viers Oph Conf, Scott and White Hospital, Temple, TX, 23-24 Feb  
96

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- Surg/Oph**      PR    **Sepanski, G; Bauman, WC; Shepard, E**  
Measuring the concentrations of perfluoropropane and sulfahexafluoride prior to  
air-fluid gas exchange  
15th Alamo City Conf, UTHSC, 1-2 Mar 96
- PR    **Barnes, S; Bauman, W**  
A prospective randomized clinical trial comparing Prednisolone 1% to Diclofenac  
0.1% in the treatment of pseudophakic cystoid macular edema (PCME)  
15th Alamo City Conf, UTHSC, 1-2 Mar 96
- PR    **Bauman, W; Casey, P; Kelly, P; Giovannini, W; Dunlap, W**  
Outcome measures in diabetic retinopathy screening  
15th Alamo City Conf, UTHSC, 1-2 Mar 96
- PR    **Bauman, WC**  
Surgical management of patients with idiopathic and ocular histoplasmosis  
subfoveal choroidal neovascularization  
16th Biennial Walter Reed Oph Postgraduate Crs, USUHS, Bethesda, MD, 18-19  
Mar 96
- PR    **Bauman, WC**  
Management of intraoperative cataract complications  
USUHS Tri-svc Cataract Crs, USUHS, Bethesda, MD, 21 Mar 96
- PR    **Bauman, WC**  
Review of retina and vitreous  
2nd Ann BAMC Oph Rev Crs, FSHT, 25-29 Mar 96
- PR    **Bauman, WC**  
Ophthalmic med readiness tng in the post-cold war era  
43rd AF Clin Surgeons Mtg, SA Conv Cen, 31 Mar-5 Apr 96
- PR    **O'Hara, M**  
Anterior segment disorders of childhood  
Oph Grand Rounds, UTHSCSA, 12 Jan 96
- PR    **O'Hara, M**  
Pediatric ophthalmology and strabismus review  
Oph Review Crs, San Antonio, TX
- PR    **O'Hara, M**  
Pediatric ophthalmology: What to refer and where to refer it  
Randolph AFB Primary Care Noontime Lecture Series, 8 Feb 96
- PR    **O'Hara, M**  
What to refer and when to refer it in pediatric ophthalmology  
Pediatric Grand Rounds, UTHSCSA, 1 Mar 96
- PR    **O'Hara, M**  
Moderator section on pediatric ophthalmology and strabismus  
Alamo City Oph Conf 1 Mar 96

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**Surg/Oph      PR    Bauman WC**

Management of retained intraocular foreign bodies in penetrating ocular injuries

USUHS, Bethesda MD, 21-24 May 96

**AB    Sepanski GJ, Campagna JA**

The medical management of glaucoma: A cost analysis

Assn for Rsch in Vision and Ophthalmology, Ft Lauderdale FL, 21-25 Apr 96

**AB    Doe EA, O'Hara MA, Jones PE, Brown S**

A comparison of prophylactic ondansetron vs prochlorperazine for strabismus repair

Assn for Rsch in Vision and Ophthalmology, Ft Lauderdale FL, 21-25 Apr 96

**AB    Casey P, Kelly P, Giovannini J, Dunlap W, Bauman W**

Outcome measures in diabetic retinopathy screening

Assn for Rsch in Vision and Ophthalmology, Ft Lauderdale FL, 21-25 Apr 96

**AB    Pahelmier NE, Holck D, Weihly S, Dutton JD**

Changes in astigmatism after blepharoptosis surgery measured by corneal topography

Assn for Rsch in Vision and Ophthalmology, Ft Lauderdale FL, 21-25 Apr 96

**AB    Barnes S, Dunlap W, Bauman W**

A prospective randomized clinical trial comparing topical prednisolone 1% to diclofenac 0.1% in the treatment of pseudophakic cystoid macular edema (PCME)

16th Ann Alamo City Ophthalmology Clin Conf, San Antonio TX, 1-2 Mar 96

**Surg/Ortho      PU    Presnal, B; Chillag, K**

Radiohumeral arthrodesis for salvage of failed total elbow arthroplasty

Jour of Arthroplasty 1995;10(5):699-701

**Surg/Oto      PR    Liening, D**

The effects of linear acceleration on distortion product otoacoustic emission in human ears

2nd Biennial International Sym on Modern Problem of Phys & Path of Hearing ,  
Moscow RUSSIA, Oct 95

**PR    Teller, D**

Middle third of the nose

Southern Med Assn Ann Mtg, Kansas City KS, Nov 95

**PR    Will, M**

A comparison of cephalometric analysis with ethnicity in obstructive sleep apnea syndrome

Southern Med Assn Ann Mtg, Kansas City KS, Nov 95

**PR    Wassmuth, E**

Thyroid carcinoma in the pediatric military population

Southern Med Assn Ann Mtg, Kansas City KS, Nov 95

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**Surg/Oto**      PR    **McGarrah, P**

An unusual presentation of a thymic cyst  
Southern Med Assn Ann Mtg, Kansas City KS, Nov 95

PR    **Teller, D**

Mid-forehead/brow lift  
Southern Med Assn Ann Mtg, Kansas City KS, Nov 95

PR    **Dickerson, E**

Nocturnal emesis: Unusual presentation of obstructive sleep apnea in a child  
Southern Med Assn Ann Mtg, Kansas City KS, Nov 95

PR    **Teller, D**

Mid-forehead/brow lift  
Grand Rounds, UTHSCSA, Dec 95

PR    **Liening, D**

Biomaterials and ossiculoplasty  
Grand Rounds, UTHSCSA, Dec 95

PR    **Bonilla, J**

Update in pediatric sinusitis  
Grand Rounds, UTHSCSA, Dec 95

AB    **Vories, A; Ramirez, S**

Squamous cell carcinoma of the lacrimal sac treated by medial maxillectomy  
Southern Med Assn of Otolaryngologists, Kansas City, Nov 95

AB    **McGarrah, P**

An unusual presentation of a thymic cyst  
Southern Med Assn of Otolaryngologists, Kansas City, Nov 95

AB    **Wassmuth, E; Ramirez, S**

Thyroid carcinoma in the pediatric military population  
Southern Med Assn of Otolaryngologists, Kansas City, Nov 95

AB    **McGarrah, P**

Post-traumatic cervical osteophytosis  
Southern Med Assn of Otolaryngologists, Kansas City, Nov 95

AB    **Dickerson, E**

Nocturnal emesis: Unusual presentation of "Obstructive sleep apnea in a child"  
Southern Med Assn of Otolaryngologists, Kansas City, Nov 95

AB    **Teller, D**

Middle third of the nose  
Southern Med Assn of Otolaryngologists, Kansas City, Nov 95

**Surg/Per Vas**    PU    **Murray, SP; Rammos, T; Stoney, RJ**

Surgery of celiac and mesenteric arteries  
Haimovici's Vasc Surg 1996, Bk Chap:982-995

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**Surg/Per Vas**    PU    **Hanson KJ, Murray SP, Stoney RJ**

Visceral ischemic syndromes in vascular medicine

**Surg/Urol**        PU    **Shandera, K; Thompson, I; Wong, R; et.al.**

Delayed development of mid-ileal conduit stenosis: The importance of life-long urologic follow-up

Southern Med Jour 1995;88(11):1118-1120

PU    **Thompson, I**

Adenocarcinoma of the prostate

Urology International, Vol 3 #1 pg 6, Jan 96

PU    **Thompson, I**

The potential application of finasteride for chemoprevention of prostate cancer

Cancer Prevention, Vol 768, Sep 30, 1995

PU    **Rozanski, T**

Inverted Papilloma: An unusual recurrent, multiple and multifocal lesion

Jour of Urology, Vol 155, Mar 96

PU    **Andriole, GI; Thompson, IM; Goldenberg, L**

Global perspectives: Adenocarcinoma of the prostate

Urol Inter Vol 3 #1, Jan 96, pg 5

PU    **Rozanski, TA**

Inverted papilloma: An unusual recurrent, multiple and multifocal lesion

J Urol 1996; 155

PU    **Rozanski, TA; Wajno, KJ; Bloom, DA**

The remnant orchiectomy

J Urol 1996; 155:712-714

PU    **Rozanski, TA**

Inverted papilloma: an unusual recurrent, multiple and multifocal lesion

J Urol 1996; 155:1391

PU    **Rozanski, TA; Shandera, KC; Jaffers, G**

The necessity of VCUG in the pretransplant urologic evaluation

Urology 1996; 47:198-200

PU    **Rozanski, TA; Schwartz, BF; Auman, R; Peretsman, SJ; Moul, JW; Deshon, GE;  
Hernandez, J, Trasher, JB**

Prognostic value of BMCG and local tumor invasion in stage I seminoma of the testis

J Surg Oncol 1996; 61:131-133

PU    **Lassen, PM; Mokulis, J; Caballero, ML; Quinones, D; Kearse, W**

Non-operational management of rectocutaneous fistula after perineal prostatectomy

Urol April 1996

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**Surg/Urol**      **PU**    **Thompson, IM**

Adenocarcinoma of the prostate: Expert opinion

Urol Int 1996; 2(1):5-7

**PU**    **Thompson, IM; Optenberg, SA; Jacobs, P; Stein, CR**

Use of New York Medicaid PASs with emergency surgical episodes

J Amb Care Management 1996; 19:31

**PU**    **Thompson, IM; Coltman, CA**

Screening for prostate cancer: Opportunities for prevention

Seminars in Urol Oncol 1996; 14:51

**PU**    **Thompson IM, Coltman CA**

Chemoprevention of prostate cancer

Clin Care for Prostatic Disease 1996;4:1-3

**PU**    **Thompson IM**

Survival after radical retropubic prostatectomy of men with clinically localized high grade carcinoma of the prostate

Cancer 1996;78.

**PU**    **Waguespack R, Svetec D, Fair K, Rozanski T**

Glomangioma of the penile and scrotal median raphe

J Urol 1996 (Jul);156:179

**PU**    **Hernandez J, Rozanski TA, et al**

Prostatic value of BHCG and local tumor invasion in stage I seminoma of the testis

J Surg Oncol 1996;61:131-133

**PU**    **Rozanski TA, Thompson IM**

Treatment of locally extensive but non-metastatic prostate cancer in: Medical and surgical management of prostate cancer

Middleton RG 1996 IGAU-SHOIN Medical Publishes, Inc., NY NY

**PU**    **Cornum R, Cornum K, Storm W**

Use of psychostimulants in extended flight operations: A desert shield experience

Advisory Group for Aerospace Research & Development 1996; AGARD-CP-579

**PR**    **Cornum, RL; Bandy, C; Martin, R**

Effect of phosphoenolpyruvate treated blood on oxygen availability in dogs

South TX Chap of Amer Col of Surgeons, San Antonio, TX, 15 Mar 96

**PR**    **Dunlap, WA**

Macular degeneration

Ann Mtg JCAH Personnel in Oph, Atlanta, GA, 2 Nov 95

**PR**    **Dunlap, WA**

Macular degeneration

UTHSCSA Combined Lecture Series, 21 Apr 95

**PUBLICATIONS - PRESENTATIONS & ABSTRACTS**  
**FISCAL YEAR 1996**

**Surg/Urol**      PR    **Dunlap, WA**

Current use of vitreous substitutes

Walter Reed Ann Oph Mtg, Bethesda, MD, 19 Mar 96

PR    **Mebust WK, Montague DK, Thompson IM**

Report on prostate cancer and impotence guidelines

Amer Urol Assn 91st Annual Mtg, Plenary Session II, Orlando FL, 6 May 96

PR    **Rozanski, T**

Voiding dysfunction in children

Pediatrics for the Practitioner 33d Teaching Conf, San Antonio TX, 14 Jun 96

PR    **Cornum, Peretsman**

Influence of surgical approach on positive margins rate following radical prostatectomy

AUA 7 May 96

PR    **Cornum, R**

Military medicine-Adventures & misadventures

Dept of Surg Grand Rounds Univ of MN 4 May 96

PR    **Curlee JE, Morris MJ, Salvador C, et al**

BALF TGF-b AND IL-6 levels in nude mice with chronic TNF-a induced pulmonary fibrosis

Amer Thoracic Soc Ann Mtg, New Orleans LA, 22 May 96

PR    **Mebust WK, Montague DK, Thompson IM**

Report on prostate cancer and impotence guidelines

Amer Urol Assn Ninety-First Annual Mtg, Plenary Session II, Orlando FL, 6 May 96

PR    **Schow Douglas**

The use of neoadjuvant anti-androgen therapy prior to radical prostatectomy for localized prostate cancer

Urology Grand Rounds Univ of MN, Jul 96

PR    **Waguespack Robt**

Clinical application of the Bosniak classification for renal cysts

South Central Section of AUA Mtg, Vail CO, 11 Sep 96

AB    **Friedrichs P, Wojcik B, Optenberg S, Thompson I, et al**

A long-term study of the efficacy of treatment of localized prostate cancer

J Urol 1996 (May Supplement) 155:401A

AB    **Svetec DA, Canby ED, Thompson IM, Sabanegh ES Jr**

The effect of parenteral testosterone replacement on prostate specific antigen (PSA) in hypogonadal men with erectile dysfunction

J Urol 1996 (May Supplement) 155:468A



**PUBLICATIONS - PRESENTATIONS & ABSTRACTS**  
**FISCAL YEAR 1996**

- Surg/Urol**      **AB**    **Cornum RLS, Thompson IM, Peretsman SJ**  
Influence of surgical approach on positive margins following radical prostatectomy  
J Urol 1996 (May Supplement) 155:555A
- AB**    **Schow D, Rozanski T, Thompson I, Harris M**  
Radical perineal prostatectomy (RPP) and neoadjuvant hormonal therapy for localized prostate cancer (CAP)  
J Urol 1996 (May Supplement) 155:646A
- AB**    **Mokulis J, Thompson I**  
Teaching and learning radical meeting: prostatectomy (RP) in the era of managed care  
J Urol 1996 (May Supplement) 155-680A
- AB**    **Cornum R, Bowersox J**  
Telepresence: A 21st century interface for urologic surgery  
AUA 6 May 96
- AB**    **Curlee JE, Morris MJ, Salvador C, et al**  
BALF TGF-b AND IL-6 levels in nude mice with chronic TNF-a induced pulmonary fibrosis  
Slide Pres at TX Thoracic Soc Ann Mtg, Austin TX, 19 Apr 96
- AB**    **Friedrichs Paul, Rozanski Thomas**  
The use of drains in patients undergoing radical prostatectomy  
South Central Section Mtg of AUA, Vail CO, Sep 96
- AB**    **Optenberg S, Thompson I, Friedrichs P, Wojcik B, Kramer B**  
Race, treatment and long-term survival from prostate cancer in an equal-access medical delivery system  
J Urol (May Supplement) 155:468A, 1996

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-88-018      REPORT DATE: 11/01/96      STATUS: Ongoing  
TITLE: Development of an Indirect Chemiluminogenic Enzyme Linked Immunoassay (CELIA) for  
Demonstrating Conformational Changes in a Model Protein

START DATE: 12/16/88      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Merrill, Gerald A.  
ASSOCIATE INVESTIGATOR: Horowitz, Paul M.

DEPARTMENT/SERVICE: Clin Inves      FACILITY: BAMC  
KEY WORDS: immunoassay;Celia;changes;protein;  
NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To develop monoclonal antibodies to rhodanese, a well characterized model protein, and use these antibodies in the development of an indirect soluble chemiluminescent enzyme linked assay system. to assess the binding affinities of anti-rhodanese monoclonal antibodies for their epitomes and demonstrate conformational changes involving the rhodanese epitomes by monitoring changes in binding affinities.

### TECHNICAL APPROACH:

The study plan is to develop a series of antibodies to use in an attempt to better understand the structure-function relationships of a model protein, rhodanese (thiosulfate; cyanide sulfurtransferase). Knowledge of the relationships of between protein structure and protein functions will provide insight into the manipulation of proteins that have medical relevance, including hormones and enzymes. Such knowledge might then permit synthesis via genetic engineering of designer rescue proteins that could be used therapeutically.

Progress cont: release factor 2-mediated termination of the UGA termination codon in th coding sequence of rhodanese. It is suggested that the N-terminal peptide inhibits the binding of the release factor to ribosomes. These data appear to provide the first report of differential inhibition of the termination reaction on ribosomes without inhibition of the peptidyltransferase reaction and peptide elongation.

Nov 96: No change (Mr. Chapa).

### PROGRESS:

Dec 95: A peptide consisting of the 17 N-terminal amino acids of rhodanese in combination with the chaperonin DnaJ specifically inhibits release factor-dependent and stop codon-dependent hydrolysis of N-formylmethionine from N(formyl)-methionyl-tRNA bound (via AUG sequence) to salt-washed ribosomes. Neither the peptide nor the DnaJ can achieve this inhibitory effect independently. The total amount of rhodanese synthesized in the cell-free coupled transcription-translation system is reduced by this 17 bamino acid peptide, with concomitant accumulation of full-length enzymatically inactive rhodanese polypeptides on rhibosomes. In combination with DnaJ, the N-terminal peptide inhibits the termination and release of full-length rhodanese peptides that have accumulated on E. coli ribosomes during the course of uninhibited coupled transcription-translation in the cell-free system. This inhibition appears to involve (cont above)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-004

REPORT DATE: 01/01/96

STATUS: Ongoing

TITLE: Development of a Bioluminescent Assay of Extreme Sensitivity for Detection and Quantitation of Ricin

START DATE: 11/16/90

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Merrill, Gerald A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Clin Inves

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To develop a solid phase enzyme-linked sandwich assay of high sensitivity for the detection and quantitation of ricin which is based on avidinbiotin technology, enzymatic generation of ATP, and the sensitivity of photon counting detection of ATP via the bioluminescent luciferin-luciferase (firefly).

### TECHNICAL APPROACH:

A solid phase enzyme linked immunoassay for quantitation of ricin utilizes the chemiluminescence of a luminol derivative which emits light at alkaline pH following the removal of a phosphate group by the action and concentration of the toxin which may be present in very low concentrations. The quantitation of ricin that is immobilized involves addition of biotinylated antiricin followed by excess avidin-alkaline phosphatase which binds to biotin very tightly. The quantitation of the alkaline phosphatase can be either colorimetric or can be measured via luminescent methods with increased sensitivity using AMPPD as the substrate.

### PROGRESS:

Nov 95: Partial funding from USAMRIID has been obtained and reagents ordered. Initial implementation of assay modifications is anticipated in Nov 95. Publications: Detection of Ricin by Colorimetric & Chemiluminescent ELOISA; Mark A. Poli, Victor R. Rivera, John Hewetson & Gerald A. Merrill; Toxicon 94 32:1371-7.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-020 REPORT DATE: 02/01/96 STATUS: Ongoing

TITLE: Establishment of a Polymerase Chain Reaction (PCR) Nucleic Acid Amplification Capability Within the Department of Clinical Investigation, BAMC

START DATE: 02/01/92 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Seal, Lawton

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Clin Inves FACILITY: BAMC

KEY WORDS: Polymerase; Nucleic Acid Amplification

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To establish a working PCR gene amplification capability. It will result in the capability to specifically amplify a positive control bacteriophage gene without contamination by irrelevant nucleic acids. Demonstration of the desired product will include separation of the amplification products by agarose gel electrophoresis and identification by product size as seen after ethidium bromide staining.

### TECHNICAL APPROACH:

No subjects involved. Controls for the reaction are contained within the kits and include a distilled water negative control and a specific bacteriophage gene positive control. Experimental design/methods; data collection and details included in protocol.

### PROGRESS:

The initial PCR was successfully accomplished and resulted in the contamination-free amplification of a Lambda bacteriophage gene. Continuing to optimize those reactions as well. Analysis of amplification products by agarose gel electrophoresis and ethidium bromide staining has been successful and both this and PCR are being taught to DCI staff.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-095      REPORT DATE: 06/01/96      STATUS: Ongoing

TITLE: Inoculation with Pentavalent (ABCDE) Botulinum Toxoid

START DATE: 07/16/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Longfield, Jenice N.

ASSOCIATE INVESTIGATOR: Merrill, Gerald

DEPARTMENT/SERVICE: Clin Inves      FACILITY: BAMC

KEY WORDS: Inoculation with Pentavalent (ABCDE) Botulinum Toxoid

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

Immunization of one volunteer who will be working with botulism toxin at Fort Detrick, MD.

### TECHNICAL APPROACH:

The purpose of this study is to determine whether it is possible for physicians familiar with central line placement are able to differentiate arterial from venous source by visual inspection of the blood in a syringe. The blood will be drawn from arterial lines and internal jugular vein catheters at four different fractional inspired oxygen concentrations to simulate those concentrations most frequently used in the operating rooms. They will be analyzed under low light and bright light conditions by anesthesiologists and surgeons.

### PROGRESS:

Jun 96: Dr. Merrill is the only patient at BAMC receiving this immunization that is required for reserve duty at USAMRIID. Last immunization was 15 Sep 95. Last titer was 9.0 IU/ml (neutralization Abs) for type A toxin. Protective titers are 0.25 IU/ml.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-025      REPORT DATE: 02/21/96      STATUS: Ongoing

TITLE: Automated Screening of Western Blot Densitometer Scans for the Detection of Type-Specific Herpes Virus Antibodies

START DATE: 02/06/91      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Ward, John A.

ASSOCIATE INVESTIGATOR: Hilliard, Julia

DEPARTMENT/SERVICE: Clin Inves

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if the application of digital signal processing and artificial neural networks (AN) can be used to distinguish B virus antibodies from herpes simplex antibodies in human sera. Logistic regression and cluster analysis will be used to select the most effective combination of preprocessing algorithms for training ANNs.

### TECHNICAL APPROACH:

Train ANNs with an input consisting of preprocessed densitometer scans of western blots (WBs) from serum samples run against B virus antigen. Preprocessing involves the application of signal analysis techniques: mapping the densitometer scans to a common molecular weight axis, filtering to remove high and low frequency noise and emphasize peaks, normalizing to eliminate amplitude distortion, windowing to zero the high and low molecular weight ends of the scan, and cross-correlating and aligning the signals to eliminate phase shifting.

### PROGRESS:

Feb 96: The workload during 95 prevented the herpes B virus diagnostic resource lab from providing the research samples described in the technical approach. Instead, archived diagnostic human serology samples were used to evaluate preprocessing techniques. Algorithms for computing and comparing cross-correlation coefficients, amplitude ratios, band counts, first derivatives and descriptive statistics were evaluated. No single algorithm was completely satisfactory. Reorganization of the lab has made it likely that rsch samples will be provided in 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-091 REPORT DATE: 01/01/96 STATUS: Terminated

TITLE: Molecular Detection of Bloodborne Pathogens in Blood for Transfusion with Emphasis on Hepatitis C

START DATE: 10/07/91 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Yeager, Curtis L.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Clin Inves FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To develop methods which combine the speed and precision of robotics and the high sensitivity and specificity of gene amplification strategies to detect RNA from the hepatitis C virus in 300 units of volunteer donor blood daily.

### TECHNICAL APPROACH:

Rsch in this proposal is designed to adapt gene amkplification techniques to a clinical diagnostic format cpable of operating at a process level (300 plus tests per day). Rsch to be conducted includes identification and development of unique nucleic acid probes and primers, testing of amplification techniques, development of solid phase nucleic acid capture assays, etc.

### PROGRESS:

Awaiting approval of rsch funding by Medical Research and Development Command.  
Oct 95: All PIs have PCSd; study terminated.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-075 REPORT DATE: 01/01/95 STATUS: Terminated

TITLE: Evaluation of Terry Fox Metho-Cult H433 and Gibco BRL Human Bone Marrow Stem Cell  
Differentiation Media

START DATE: 03/01/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Davey, Enid

ASSOCIATE INVESTIGATOR: Vukelja, Svetislava J.

DEPARTMENT/SERVICE: Clin Inves FACILITY: BAMC

KEY WORDS: Bone marrow stem cells, Gibco BRL Medium

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if Gibco BRL Medium supports greater differentiation of bone marrow stem cells than Terry Fox Medium.

### TECHNICAL APPROACH:

The study will be conducted in two phases as outlined in protocol.

### PROGRESS:

Mar 96: Drug company no longer makes one of the reagents; study never initiated (MS Reeb).



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-094 REPORT DATE: 01/01/96 STATUS: Terminated

TITLE: Dietary Protein Needs and Protein and Amino Acid Metabolism of Military Women and Men

START DATE: 06/21/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Motil, Kathleen J.

ASSOCIATE INVESTIGATOR: Morales, Yeager

DEPARTMENT/SERVICE: Clin Inves

FACILITY: BAMC (Baylor)

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Twofold: 1. To assess whether neuropsychological functions can discriminate individuals with primary alcoholism/secondary ASP from individuals with primary ASP/secondary alcoholism and, 2. to clarify, to the extent that such will be possible, through neuropsychological assessment the brain structures (lobes) associated with ASP and alcoholism.

### TECHNICAL APPROACH:

The subject samples will be composed of six groups (1) alcoholics without ASP (ALC), (2) ASP without alcohol and/or drug problems (ASP), (3) primary alcoholics with secondary ASP (ALC+ASP), (4) primary ASP with secondary alcoholism (ASP+ALC), (5) a control group composed of patients with frontal lobe dysfunctions and without an antisocial personality disorder, and (6) a second control group composed of individuals who are antisocial but who do not have an antisocial personality disorder.

### PROGRESS:

Nov 95: Study terminated because lack of funding. Should funding status of this protocol change, reinstatement will be requested.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-126      REPORT DATE: 07/01/96      STATUS: Ongoing

TITLE: Investigation of Possible Changes in the Concentration of Soluble Leukocyte Selectin (sL-selectin) in Stored Blood

START DATE: 08/16/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Bradley, Melville (Path Res)

ASSOCIATE INVESTIGATOR: Merrill, Longfield, Smith

DEPARTMENT/SERVICE: Clin Inves

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To see whether sL-selectin concentrations increase over time in stored blood (at 0 hr and at 48 hr), and if so, to speculate about its possible role in contributing to the phenomenon of post-transfusion immunosuppression. The null hypothesis of this study is that there will not be an increase in sL-selectin concentrations in stored blood over time.

### TECHNICAL APPROACH:

As outlined in the protocol.

### PROGRESS:

Jul 96: The plasma has become available since June and will be ordered. Plan to run samples in Aug 96. Should be starting to enroll the anticipated 15 patients about Sep 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-143      REPORT DATE: 09/01/96      STATUS: Ongoing

TITLE: Design and evaluation of rapid assays for select antibody and antigen specificities throughout the course of B virus infection

START DATE: 10/01/95      ESTIMATED COMPLETION DATE: 09/01/00

PRINCIPAL INVESTIGATOR: Ward, John A.

ASSOCIATE INVESTIGATOR: Hilliard, Katz

DEPARTMENT/SERVICE: Clin Inves

FACILITY: BAMC/SFBR

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

To evaluate rapid assays designed to identify selected antibody and antigen specificities throughout the course of infection.

TECHNICAL APPROACH:

Specifics are outlined in protocol.

PROGRESS:

Sep 96: This protocol is awaiting funding by NIH. The anticipated start date is shown as Sep 96 in the application for a clinical investigation protocol.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-045 REPORT DATE: 02/22/96 STATUS: Ongoing

TITLE: An In Vitro Assessment of the Antineoplastic Potential of 2H-1, 3-Oxazine-2, 6(3H) -Dione (3-Oxauracil)

START DATE: 02/07/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Seal, Lawton A.

ASSOCIATE INVESTIGATOR: CTRC

DEPARTMENT/SERVICE: Clin Inves

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess the cytotoxic effects of 3-Oxauracil (OU) on human tumor cell lines. This study will delineate OU's capacity to inhibit the proliferation of selected human tumor lines. A favorable outcome would justify additional in vitro or in vivo investigations.

### TECHNICAL APPROACH:

The null hypothesis is: OU treatment has no effect on human tumor cell proliferation. To test this hypothesis six human tumor cell lines will be exposed to various concentrations of OU and the amount of cell growth monitored.

### PROGRESS:

No report available as of this date. Annual review due Dec 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-098      REPORT DATE: 10/01/96      STATUS: Ongoing

TITLE: Metabolic Pathogenesis of Fibromyalgia Syndrome: #3. Platelet Serotonin and Spinal Fluid Neuropeptides

START DATE: 08/06/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Seal, Lawton A.

ASSOCIATE INVESTIGATOR: Russell, I. Jon

DEPARTMENT/SERVICE: Clin Inves

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To continue to expand the biological fluid sample bank by collecting urine, plasma, serum, and CSF samples from healthy normal controls; from FS patients without and with other medical conditions; from non-FS patients with those same medical conditions including diabetics with and without painful diabetic neuropathy. The non-FS samples will be used as controls for the FS to establish CSF test sensitivity and specificity.

### TECHNICAL APPROACH:

Detailed specifics are outlined in protocol.

### PROGRESS:

Annual review due Jun 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-003      REPORT DATE: 09/01/96      STATUS: Completed

TITLE: 5-Fluorouracil Iontophoretic Therapy for Bowenoid Conditions

START DATE: 10/26/92

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: McCollough, Martha L.

ASSOCIATE INVESTIGATOR: Giandoni, Martin; Grabski, William

DEPARTMENT/SERVICE: Derm

FACILITY: BAMC

KEY WORDS: 5-Fluorouracil; Iontophoretic; Bowenoid

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 26

### OBJECTIVES:

To determine if the iontophoresis of 5-fluorouracil (5-FU) is an effective treatment for Bowen's disease and/or bowenoid actinic keratoses.

### TECHNICAL APPROACH:

As outlined in the protocol.

### PROGRESS:

Oct 95: 27 patients with 29 lesions have been treated with iontophoresis of 5-FU. No complications noted and the treatment was well tolerated by all patients. Continuing to enroll. No funding requirement.

Sep 96: Total of 26 patients with 25 cures. Paper being written (Dr. McCullough)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-122      REPORT DATE: 09/01/96      STATUS: Terminated

TITLE: A Single Blinded Study Comparing Nightly Versus Every Other Night Versus Weekly Application of Retin-A 0.05% Cream for the Treatment of Comedonal Acne Vulgaris"

START DATE: 10/01/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Conger, Leo A.

ASSOCIATE INVESTIGATOR: Elston, Dirk M; Peake, Mark; Keller, Rick

DEPARTMENT/SERVICE: Derm      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 32

### OBJECTIVES:

To compare the cost, efficacy and side effect profiles of nightly application versus every other night application versus weekly application of Retin-A cream for the treatment of comedonal (blackheads and whiteheads) acne vulgaris.

### TECHNICAL APPROACH:

At present, the standard treatment with Retin-A involves applying the cream each night to the entire affected area. Preliminary observations suggest that less frequent applications may still be effective therapy, with less irritation and lower cost. Further specifics outlined in protocol.

### PROGRESS:

Oct 95: Recuriting continues to be dismal, little to no progress since last years' review.

Sep 96: Dr. McCollough reports that Dr. Conger has transferred to Darnall ACH and because of lack of enrollment, study has been discontinued at both facilities.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-004 REPORT DATE: 01/01/96 STATUS: Terminated

TITLE: Growth of Human Basal Cell Carcinoma Cells in defined Medium and Study of Their Growth and Immunologic Characteristics

START DATE: 10/20/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Anderson, Lawrence

ASSOCIATE INVESTIGATOR: Grabski, WJ; Grimwood, RE

DEPARTMENT/SERVICE: Derm FACILITY: BAMC

KEY WORDS: keratinocyte growth medium, epidermal growth factor, basal cell

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 6

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

The growth and study of basal cell carcinoma cells in culture.

### TECHNICAL APPROACH:

The defined medium for basal cell growth will consist of keratinocyte growth medium complete with epidermal growth factor, bovine pituitary extract, insulin, hydrocortisone and anti-microbial agents. This is a modified MCDB 153 formulation that is serum free and comes augmented with growth factors as stated. Further specifics outlined in protocol.

### PROGRESS:

Oct 95: Due to lack of technical support staff no additional patients have been enrolled. No additional progress to report.

Jul 96: Dr. Angeloni reported that Dr. Anderson has left the military, no one else at BAMC or Wilford Hall Med Cen is pursuing this study; therefore terminate.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-055 REPORT DATE: 02/21/96 STATUS: Terminated

TITLE: A Single-Blinded Study Comparing Nightly Versus Every Other Night Versus Weekly Application of Retin-A 0.05% Cream for the Treatment of Comedonal Acne Vulgaris

START DATE: 02/07/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Biediger, Tracy L.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Derm FACILITY: BAMC

KEY WORDS: Retin-A 0.05% Cream, comedonal acne vulgaris

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 30

### OBJECTIVES:

To compare the cost, efficacy and side effect profiles of nightly application versus every other night application versus weekly application of retin-A cream for the treatment of comedonal (blackheads and whiteheads) acne vulgaris.

### TECHNICAL APPROACH:

At present, the standard treatment with Retin-A involves applying the cream each night to the entire affected area (e.g., the face, chest, and/or back). This method has been generally successful in reducing the number of acne lesions, especially open and closed comedones. Irritation is a common side effect of nightly retin-A therapy. Preliminary observations suggest that less frequent applications may still be effective therapy, with less irritation and lower cost.

### PROGRESS:

Feb 96: PI was reassigned Darnall Army Hospital. Dr. Becker reports no adverse affects encountered with the 30 patients studied. Study is considered terminated as no other physician interested in pursuing it.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-095      REPORT DATE: 01/01/95      STATUS: Completed

TITLE: The Effect of Acemannan on UVB-Induced Erythema

START DATE: 05/09/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Angeloni, Vincent L.

ASSOCIATE INVESTIGATOR: Elston, Dirk; Vinson, Richard

DEPARTMENT/SERVICE: Derm      FACILITY: BAMC

KEY WORDS: Acemannan UVB-Induced Erythema, banal hydrogel, double-blinded

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 12

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 12

### OBJECTIVES:

To evaluate whether topical application of acemannan has any beneficial effect on the erythema induced by ultraviolet B light (i.e. sunburn) when applied before and after light exposure. The study will utilize healthy volunteers who will be exposed to a measured dose of ultraviolet B (UVB) to small areas of non-sun exposed skin which have been treated with acemannan gel before exposure and after exposure. The resulting erythema will then be evaluated to discern any effect induced by the application of the acemannan.

### TECHNICAL APPROACH:

The hypothesis to be tested in this experiment is that acemannan applied to the skin will either attenuate the erythema induced by UVB exposure or enhance its resolution. Thus, we will evaluate the UVB responses of untreated skin, skin treated with a banal hydrogel (K-Y jelly) and skin treated with acemannan gel. Erythema responses will be quantified visually in a double-blinded fashion.

### PROGRESS:

Apr 96: Twelve patients enrolled but no significant findings; no adverse affects.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-007      REPORT DATE: 01/01/96      STATUS: Completed

TITLE: A Double Blind Study Comparing EMLA Cream to Iontophoresis of Lidocaine (Xylocaine) for Painless Induction of Cutaneous Anesthesia

START DATE: 11/21/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Menon, Padman

ASSOCIATE INVESTIGATOR: Grabski, William J; Anderson, Lawrence

DEPARTMENT/SERVICE: Derm

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 48

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 48

### OBJECTIVES:

To compare the effect of EMLA cream versus iontophoresis of 2% xylocaine (lidocaine) with 1:100,000 epinephrine to reduce/alleviate pain and discomfort associated with the needle insertion for injection of local anesthetic.

### TECHNICAL APPROACH:

48 healthy volunteers will be invited to participate in the study after obtaining an informed consent. The study will be conducted at the Derm Clinic, BAMC.

### PROGRESS:

Nov 95: Study completed, no complications noted; no patients dropped out of the study. Study was presented at the 25th Annual Meeting of the Amer Soc for Dermatologic Surgery May 95. Manuscript has been prepared.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-073 REPORT DATE: 02/08/96 STATUS: Ongoing

TITLE: A randomized, single blind study to compare the cost and efficacy of topical calcipotriene (Dovonex) with that of topical 5-fluorouracil (Efudex) for the treatment of psoriasis

START DATE: 03/20/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Deering, Karen

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Derm

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 5

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 5

### OBJECTIVES:

To compare the cost and efficacy of two drugs used for the treatment of chronic plaque-type psoriasis.

### TECHNICAL APPROACH:

Approximately 68 adult patients with stable plaque-type psoriasis involving less than 30% of body surface area (estimated using the "rule of 9's") will be randomized to receive topical treatment with either calcipotriene or 5-FU. All lesions present at baseline will be treated, except those on the face and genitalia. Baseline complete blood count and chemistry profile (M1) will be obtained. Patients with hypercalcemia or neutropenia will not be enrolled. Women of child bearing potential will not be enrolled unless they are using two effective forms of birth control. A negative serum HCG will be obtained prior to initiation of therapy, and therapy will be started on the second or third day of the following menstrual period. Prior to beginning treatment, each lesion will be outlined on plastic wrap, and the area calculated.

### PROGRESS:

Feb 96: Enrollment has been slow, in part because of the number of patients already using Dovonex prescribed by civilian practitioners. PI (Dr. Dirk Elston) is moving to Wilford Hall in March and be replaced by Dr. Karen Deering, MD, USAF, MC.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-101      REPORT DATE: 09/01/96      STATUS: Ongoing

TITLE: An Open-label Multicenter Trial to Evaluate the Safety and Effectiveness of Various Treatment Durations of Terbinafine in patients with Onychomycosis of the Toenails

START DATE: 07/25/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Keller, Richard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Derm

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 5

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 5

### OBJECTIVES:

The primary objective of the study is to evaluate the safety and effectiveness of 12, 18, or 24 weeks of therapy with 250 mg/day of terbinafine in patients with onychomycosis of the toenails. The secondary objective is to evaluate the epidemiologic aspects of toenail onychomycosis in the United States as well as changes in the quality of life associated with oral terbinafine in the treatment of onychomycosis.

### TECHNICAL APPROACH:

Patient population, inclusion/exclusion criteria, study medication, dosage/administration and further details are outlined in protocol.

### PROGRESS:

Sep 96: Four patients enrolled in study; following 3 subjects. Only have one more visit in January to complete their evaluation. No problems or adverse effects.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-111 REPORT DATE: 11/01/96 STATUS: Ongoing

TITLE: A Five-Yr Observational Study to Evaluate Clinical Response and Recurrence Rate in the Treatment of Basal Cell Ca with Fluorouracil/Epinephrine Injectable Gel

START DATE: 08/01/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Grabski, William J.

ASSOCIATE INVESTIGATOR: Powers, James

DEPARTMENT/SERVICE: Derm

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 34  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 34

### OBJECTIVES:

Primary: 1. To describe the recurrence rate 12 months after treatment in those patients with no clinical evidence of disease at Month 3 Follow-up. 2. To describe the clinical response rate of treatment with 0.5 mL 5-FU/epi injectable gel when administered three times weekly for 2 weeks in patients with basal cell carcinoma. 3. To evaluate the safety of the fluorouracil/epinephrine injectable gel when administered as described above.

### TECHNICAL APPROACH:

Study design, conduct of study, study visit requirements and parameters to be measured, etc, are covered in the protocol.

### PROGRESS:

Nov 96: Dr. Powers reports that no significant adverse effects. Two patients did develop squamous cell cancer which was reported to the IRB earlier.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-128      REPORT DATE: 07/01/96      STATUS: Ongoing

TITLE: An Open Label Study to Evaluate the Effectiveness of 1,25 Dihydroxy Vitamin D3 (ROCALTROL) in Patients Who Have Limited or Diffuse Systemic Sclerosis

START DATE: 08/17/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Pujals, John

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Derm

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

To stop the evolution of, and hopefully reverse the overproduction of collagen by fibroblasts as measured by clinical criteria.

### TECHNICAL APPROACH:

1,25 dihydroxy vitamin D3 is an FDA approved medication in routine use with indications for treatment of hypocalcemia in patients undergoing renal dialysis and for treatment of hypoparathyroidism. 1.25 dihydroxy vitamin D3 has been used in 3 foreign studies to treat systemic sclerosis (21 patients) and localized scleroderma (7 patients). The results have been promising and no adverse effects have been noted.

### PROGRESS:

Jul 96: Dr. John Pujals (670-5378) currently on a rotation at WHAFMC, reports that he is taking over as PI from former PI Jeffrey Stiles. Currently only one patient is enrolled at BAMC and that patient is going through the preliminary part of study. He is trying to contact more patients but defines process as slow going.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-055      REPORT DATE: 04/19/96      STATUS: Ongoing  
TITLE: **Dermatophyte Flora in an Outpatient Dermatology Clinic**

START DATE: 03/01/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Angeloni, Vincent L.**

ASSOCIATE INVESTIGATOR: **Keller, Richard**

DEPARTMENT/SERVICE: **Derm**      FACILITY: **BAMC**

KEY WORDS: **dermatophytic flora, fungi**

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To evaluate and compare the dermatophytic (fungi which infect skin) flora present in the current outpatient Dermatology Clinic (Bldg 1053) the new BAMC prior to move in, and the new BAMC after several months of dermatologic patient care. Hope to determine whether there is a change in the dermatophyte flora after patients are cared for in the new hospital and compare any changes in the flora to the current dermatology clinic's flora and to the flora of the new hospital prior to occupancy. To our knowledge, such a study has not been undertaken and could help identify a possible nidus for the acquisition of dermatophyte infections if the flora is noted to change such that pathogenic dermatophytic organisms are over-represented within the clinic exam rooms.

### TECHNICAL APPROACH:

This study will be conducted as an observational study. Anticipating that the dermatophyte flora in the new hospital will change after occupancy to being very similar to the current flora in the old" BAMC Derm Clinic. This will be a descriptive study.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-095      REPORT DATE: 07/15/96      STATUS: Ongoing

TITLE: Comparison of High Energy, Pulsed CO2 laser vs. Q-switched Nd:YAG (1064nm) Laser in the Treatment of Tattoos

START DATE: 08/01/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: English III, Joseph C.

ASSOCIATE INVESTIGATOR: Finley

DEPARTMENT/SERVICE: Derm

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To compare treatment efficacy of high energy, pulsed CO2 laser removal of decorative tattoos to the established use of the Q-switched Nd:YAG laser.

### TECHNICAL APPROACH:

The new high energy, pulsed CO2 laser can cause thermal destruction without thermal diffusion to surrounding tissue and has decreased the incidence of scar formation. This laser will produce a high amplitude energy wave causing disruption of pigment and eliminate the need for a selective wavelength to be absorbed in order to disrupt the pigment. It is felt this can consolidate the treatment of tattoos to one laser system, decrease the treatment time by 1/2 and decrease the cost of laser treatment. To date, there are no studies comparing these two laser systems.

### PROGRESS:

No report available as of this date. Annual review due May 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-119

REPORT DATE: 08/22/96

STATUS: Ongoing

TITLE: **An Ultrastructural Study of the Dermal-Epidermal Junction Following Skin Splitting with Various Methods**

START DATE: 02/02/91

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **David-Bajar, Kathleen**

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Derm

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

To demonstrate a reproducible site of separation, routine use of such "split skin" methods that will become the standard for the indirect immunofluorescence evaluation of bullous skin disorders.

TECHNICAL APPROACH:

Specimens of discarded human adult skin and neonatal foreskin will be subjected to dermal-epidermal separation using each of three methods: NaCl, EDTA, and dispase. Each specimen will then be processed for electron microscopy, after incubation in specific monoclonal antibodies to known anatomic components of the dermal-epidermal junction. Two investigators independently evaluate and be blinded to the source of the specimens in making their assessments.

PROGRESS:

Feb 94: For much of the last year we did not have an electromicroscopy technician. A new technician, SSG Johnson is now working on this project and has successfully processed intact neonatal skin. He is learning the split-skin techniques, and will begin working on the immunogold staining as soon as reagents are received.

Nov 96:

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-142 REPORT DATE: 10/02/96 STATUS: Ongoing

TITLE: High-Energy, Short-Pulsed Carbon Dioxide Laser Resurfacing for Prophylaxis and Treatment of Actinic Keratoses

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Laws, Richard

ASSOCIATE INVESTIGATOR: Finley

DEPARTMENT/SERVICE: Derm

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the effectiveness of the high-energy, short-pulsed CO2 laser (HESP-CO2L) as a modality for the treatment and prophylaxis of actinic keratoses.

### TECHNICAL APPROACH:

Approximately 30 adult aged patients with Fitzpatrick skin type I, II, or III (8) with moderate to severe actinic damage and at least fifteen facial AKs will be enrolled in the study. Further specifics are outlined in protocol.

### PROGRESS:

To be reviewed Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-040

REPORT DATE: 01/01/96

STATUS: Ongoing

TITLE: An Evaluation of Nafcillin for the Initial Treatment of Cellulitis

START DATE: 12/24/92

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Hunter, Curtis

ASSOCIATE INVESTIGATOR: Rodgers, Kevin

DEPARTMENT/SERVICE: Emerg Med

FACILITY: BAMC/WHAFMC

KEY WORDS: Nafcillin; Cellulitis

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 10

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

To evaluate the effectiveness of oral antibiotics in treating cellulitis and preventing subsequent admission of patients with cellulitis. Compare the efficacy of an initial parenteral dose of antibiotics in preventing the subsequent admission of patients with cellulitis, as compared to those patients who do not receive parenteral antibiotics. Compare the efficacy of an initial dose of parenteral antibiotics in treating more rapidly those patients with cellulitis, as compared to those patients who do not receive antibiotics.

### TECHNICAL APPROACH:

This will be a randomized, prospective study. Patients with cellulitis deemed appropriate for outpatient therapy will be randomized at the beginning of the study to one of two treatment regimens. Patient eligibility, exclusion criteria and study plan outlined in protocol.

### PROGRESS:

Dec 95: Original PI Chris Hunter has PCSd. Currently looking for someone to continue study and serve as PI.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-010      REPORT DATE: 10/01/96      STATUS: Ongoing  
TITLE: Comparison of Outpatient Treatments for Pyelonephritis

START DATE: 10/01/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Hemphill, Robin

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Emerg Med      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

This study will attempt to show the safety of outpatient management of acute pyelonephritis using either combined IV and oral medications vs oral medications alone. The population studied will be healthy males and females using IV gentamicin plus oral bactrim, vs oral bactrim alone.

### TECHNICAL APPROACH:

The hypothesis is to prove that outpatient management of healthy individuals with pyelonephritis is both safe and effective using a two week course of either oral plus IV antibiotics, or using oral antibiotics alone. Men and women presenting to the Emergency Department with signs and symptoms suggestive of pyelonephritis will be considered for the study.

### PROGRESS:

Oct 96: Following the six patients and learning this is a very interesting study. No adverse reactions except for minor allergy.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-035      REPORT DATE: 01/01/96      STATUS: Completed

TITLE: **HOOD Evaluation of Albuterol Metered Dose Inhaler Effects on Serum Potassium Levels in Healthy Adults: A Prospective Study**

START DATE: 01/28/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Gerhardt, Robert T.**

ASSOCIATE INVESTIGATOR: Brace, R; Coppola, M

DEPARTMENT/SERVICE: Emerg Med - DAH      FACILITY: BAMC

KEY WORDS: Albuterol, Metered Dose Inhaler (MDI)

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This study is designed to determine whether the inhalation of albuterol from a portable, metered-dose inhaler (MDI) system causes clinically significant decreases in serum potassium levels in normal, healthy adults, and further, to quantify the extent and duration of such a decrease.

### TECHNICAL APPROACH:

Healthy male and female adult volunteers aged 18 to 50 will be recruited for participation. It is estimated that a total of 24 subjects (8 per experimental group) will be needed to obtain significance under this study's design (see Design & Methods in protocol).

### PROGRESS:

Waiting for drug company to come through with placebo.

Jan 96: Received notification that study is complete but no data furnished from DAH.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-036      REPORT DATE: 03/20/95      STATUS: Completed  
TITLE: Follow-up Compliance for Febrile Children

START DATE: 02/01/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Hemphill, Robin R.

ASSOCIATE INVESTIGATOR: Morgan, J. Alan; Santen, Sally A.

DEPARTMENT/SERVICE: Emerg Med      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 150  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 150

### OBJECTIVES:

To determine the rates of compliance to follow-up in a population of febrile children. (NULL Hypothesis: Parents of febrile children will not follow-up as directed by the physician when they have to make their own appointments.)

### TECHNICAL APPROACH:

The hypothesis of this study is that the parents of ill children in the military have access to free medical care, but it may not be this free care that causes the military to have better rates of follow-up compliance than civilian institutions. Rather, it may be that the military system previously studied made specific follow-up appointments for children. This meant that the parents had no responsibility to try to contact a physician to arrange follow-up appointments. We now want to study whether the rates of follow-up compliance decrease when the care remains free, but the parents must make more of an effort to arrange their own follow-up. Children presenting to the Brooke Army Medical Center Emergency Department with an acute febrile illness, who are later discharged, will be considered for this follow-up study.

### PROGRESS:

Mar 96: Study is complete. Presented at ACEP research forum. Paper for publication being written.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-127

REPORT DATE: 07/01/96

STATUS: Ongoing

TITLE: Use of H1/H2 Blockers in Treatment of Acute Urticaria

START DATE: 08/16/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Brooks, Michael

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Emerg Med

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 16

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 16

### OBJECTIVES:

To compare the efficacies of oral cimetidine and diphenhydramine alone and in combination for the treatment of acute urticaria.

### TECHNICAL APPROACH:

A prospective, randomized, double-blind study will be instituted. Will utilize any patient at least 18 years of age or any active duty personnel with acute urticaria of any etiology and of any duration. All subjects will be treated in compliance with all applicable FDA and HHS guidelines. Exclusion criteria, and detailed specifics are outlined in protocol.

### PROGRESS:

Jul 96: To date a total of 16 patients have been enrolled in the study. Only one patient noted worsening symptoms and returned to a civilian emergency room for care. That person was removed from the study as per the protocol's requirements. No complications, misadventures or adverse drug reactions were noted.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-064 REPORT DATE: 05/01/96 STATUS: Ongoing

TITLE: **Is Haloperidol an Effective Treatment for Patients Presenting with Migraine Headaches to the Emergency Department?**

START DATE: 05/07/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Davison, Maria

ASSOCIATE INVESTIGATOR: Sheridan, Morgan

DEPARTMENT/SERVICE: Emerg Med

FACILITY: BAMC /WHMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

To explore the use of IV haloperidol in treating migraine headaches in adult patients presenting to the emergency department.

TECHNICAL APPROACH:

Inclusion/exclusion criteria, risks/discomforts/safeguards, alternative treatments, etc, outlined in protocol.

PROGRESS:

No report available as of this date. annual review due Dec 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-090 REPORT DATE: 10/29/96 STATUS: Ongoing

TITLE: **Diagnostic Efficacy of Troponin T in Diagnosing Acute MI and Correlation of Positive Troponin T Levels in Patients with Acute MI and Unstable Angina with Incidence of In-hospital Complications**

START DATE: 07/02/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Colo, Andrea J.

ASSOCIATE INVESTIGATOR: Elmore, Hemphill, Modlin, Baddour

DEPARTMENT/SERVICE: Emerg Med

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To determine the sensitivity, specificity and positive and negative predictive values of Troponin T in the diagnosis of acute MI. Also, to establish a receiver-operating characteristic curve, and to determine the optimum reference range for the population of patients at BAMC. Population studied would include all patients admitted to the hospital for evaluation of possible cardiac disease with a "rule-out MI" protocol in a 3 month period. 2. To determine if there is a correlation between a positive Troponin T and the incidence of in-hospital complications. 3. To determine the potential for cot reduction by triaging patients to "step-down" units, rather than intensive care units, based on Troponin T values.

### TECHNICAL APPROACH:

Descriptive study with subject description, data collection, statistical analysis and specifics outlined in protocol.

### PROGRESS:

To be reviewed June 1997.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-091      REPORT DATE: 07/31/96      STATUS: Ongoing  
TITLE: A Retrospective Review of Emergency Department Right Upper Quadrant Ultrasounds

START DATE: 07/02/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Buggs, Adrienne M.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Emerg Med      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

A major diagnostic tool for evaluating emergency department patients with pain of suspected biliary origin is the right upper quadrant ultrasound. Ultrasound is quite sensitive for demonstrating the presence of gallstones, diagnosing acute cholecystitis and demonstrating dilatation or obstruction of the biliary tree. Because it is also able to accurately detect many non biliary conditions, ultrasonography is considered by many to be the initial radiographic study of choice for evaluating patients with right upper quadrant pain.

### TECHNICAL APPROACH:

While there are other studies which are more specific for diagnosing acute cholecystitis, they take a great deal of time and require the use of ionizing radiation.

### PROGRESS:

No report available as of this date. Annual review due May 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-013 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: A Randomized, Double-Blind, Placebo-Controlled Trial of the Effect of Lovastatin on the Incidence of Primary Coronary Artery Disease in Patients with Mild to Moderate Elevations in total and LDL-Cholesterol in Combination with Low HDL-Cholesterol

START DATE: 12/11/90 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Moody, Joe

ASSOCIATE INVESTIGATOR: Downs, Rick (WHMC)

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC/WHMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6605

### OBJECTIVES:

To investigate whether chronic treatment with lovastatin in patients without clinical evidence of coronary heart disease, slight to moderately elevated total and LDL cholesterol and low HDL-cholesterol will decrease the rate of fatal CHD of nonfatal myocardial infarction over a period of at least five years.

### TECHNICAL APPROACH:

Participants will be asked to maintain a standard low-fat and low-cholesterol diet throughout the study under the guidance of a dietician. Participants will be randomly assigned to either the placebo group or treatment group. The later group will receive 20 or 40 mg of lovastatin. Following initial evaluation at the Wilford Hall Wellness Clinic, they will be asked to return at six week intervals for the first eighteen months and then every six months thereafter. Lab tests will be performed at every follow-up visit.

### PROGRESS:

Jan 96: No change in PI. The associate PI at WHAFMC is now LTC Rick Downs 670-6200. Anticipate completion approximately Feb 98.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-039 REPORT DATE: 10/01/96 STATUS: Completed

TITLE: Relationship of Echocardiographic Doppler Indices of Diastolic Function to Severity of Cardiac Translant Rejection

START DATE: 12/24/02 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Boyd, Sheri Y.N.

ASSOCIATE INVESTIGATOR: Mego, David; Khan, Nancy; Rubal, Bernard, Wellford, Armistead

DEPARTMENT/SERVICE: Med/Card FACILITY: BAMC

KEY WORDS: Echocardiographic Doppler Indices; Diastolic Function

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 50

### OBJECTIVES:

To determine if serial changes in the echocardiographic Doppler A-Ar interval correlates with grades of cardiac transplant rejection.

### TECHNICAL APPROACH:

This study is a prospectively designed longitudinal study in which all cardiac transplant patients (n=25) on the transplant service at BAMC will be asked to participate. Following informed consent, 2-D doppler echocardiographic studies will be performed on patients undergoing routine right heart surveillance biopsies.

### PROGRESS:

Nov 95: Data has been analyzed for all 42 studies performed to date on 22 patients. Early data analysis is encouraging for continuing the study. Presented at ACP meeting.

Oct 96: Data analyzed; manuscript written and presented at the JESE. Study completed (Dr. Boyd).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-041 REPORT DATE: 01/01/96 STATUS: Terminated

TITLE: An Evaluation of Radionuclide Angiography and Echocardiography for Assessment of Doxorubicin Induced Ventricular Dysfunction

START DATE: 12/24/92 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Ebersole, Douglas G.

ASSOCIATE INVESTIGATOR: Jenkins, Terry; Katz, Neil; Heironimus, James

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS: Radionuclide Angiography; Echocardiography; Doxorubicin

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the effects of doxorubicin on left ventricular diastolic function and to determine if radionuclide angiographic and/or echocardiographic parameters of diastolic dysfunction reliably precede doxorubicin-induced systolic dysfunction reliably precede doxorubicin-induced diastolic dysfunction. this could allow the clinician to adjust or discontinue doxorubicin therapy before potentially irreversible loss of systolic function occurs.

### TECHNICAL APPROACH:

It is proposed that to test the hypothesis that, in patients receiving doxorubicin therapy, radionuclide angiographic and echocardiographic markers of left ventricular diastolic dysfunction reliably precede the loss of left ventricular systolic function. Specifics in protocol.

### PROGRESS:

Jan 96: Terminated due to poor enrollment.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-047      REPORT DATE: 01/01/96      STATUS: Ongoing

TITLE: Validation of a Nonlinear Three Element Model for Estimating Stroke Volume and Aortic Flow Wave  
From Morphology in Man

START DATE: 01/24/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rubal, Bernard

ASSOCIATE INVESTIGATOR: Wesseling, Karel H.; Karemaker, John M.

DEPARTMENT/SERVICE: Med/Card      FACILITY: BAMC

KEY WORDS: Stroke volume; aortic flow wave form morphology

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

To test the validity of at three-element nonlinear model for estimating aortic flow waveform morphology in man.

### TECHNICAL APPROACH:

This study will be a retrospective study in which flow waves derived from a three element non-linear Windkessel model<sup>2</sup> are compared to directly recorded electromagnetic flow/velocity waveforms. Details including data analysis included in protocol.

### PROGRESS:

Jan 96: Bioinstrumentation remains a problem in completing this protocol. It is hoped that reliable equipment will be available following transition to new BAMC.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-065      REPORT DATE: 04/01/95      STATUS: Completed

TITLE: Effect of Supportive Interventions on Patient Perception of Musculoskeletal Pain During Cardiac Catheterization

START DATE: 03/01/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Miller, Lois

ASSOCIATE INVESTIGATOR: Nottestad, Sheri Y.

DEPARTMENT/SERVICE: Med/Card Cath      FACILITY: BAMC

KEY WORDS: Musculoskeletal; Cardiac Catheterization

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To test the effect of back and arm support interventions on the patients' perception of musculoskeletal pain during cardiac catheterization.

### TECHNICAL APPROACH:

There is a need to develop methods for reducing both the musculoskeletal pain and the consequent use of analgesics and narcotics to accomplish a level of comfort during cardiac catheterization. Details are outlined in protocol.

### PROGRESS:

Apr 96: Results presented at American College of Physicians, Reston, VA, Oct 95 and at BAMC Hospital Quality Improvement Meeting Jan 96. There was a favorable trend of less back and arm pain in the experimental group. A prototype mattress has been manufactured and a larger study utilizing it is under development. A new application will be submitted to the IRB.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-066 REPORT DATE: 07/01/96 STATUS: Terminated

TITLE: Myocardial Imaging Utilizing Positron Emission Tomography to Detect and Assess Coronary Artery Disease

START DATE: 03/25/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Miller, Lois

ASSOCIATE INVESTIGATOR: Wellford, Landon; Katz, Neil

DEPARTMENT/SERVICE: Med/Card FACILITY: BAMC

KEY WORDS: Myocardial Imaging; Positron Emission Tomography; Coronary Artery

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Evaluation of the accuracy and utility of Positron Emission Tomography in the detection and assessment of coronary artery disease.

### TECHNICAL APPROACH:

Detailed specifics given in protocol.

### PROGRESS:

Feb 96: No progress made.

Jul 96: Termination requested. No patients enrolled.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-115 REPORT DATE: 07/01/96 STATUS: Terminated

TITLE: **Obstructive Sleep Apnea and Silent Myocardial Ischemia in Post-Myocardial Infarction Patients; frequency, temporal relationship and response to nasal continuously positive airway pressure (nCPAP) therapy**

START DATE: 08/01/93

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Bauch, Terry**

ASSOCIATE INVESTIGATOR: Loubé, Daniel; Peacock, Mark; Gilman, James

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

1. Identify obstructive sleep apnea in post-myocardial infarction patients with known risk factors for OSA. 2. Investigate the frequency of, and temporal relationship between episodes of OSA and Silent Myocardial Ischemia in post-MI patients. 3. Determine the effect of nCPAP treatment of OSA upon SMI in post-MI patients.

### TECHNICAL APPROACH:

Study design, population, methods and specifics covered in protocol.

### PROGRESS:

Jul 96: Study terminated during 1995. No adverse events.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-125 REPORT DATE: 07/01/96 STATUS: Terminated

TITLE: Endosconics PTCA Balloon Catheter: Eagle

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Ebersole, Douglas

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To evaluate the safety and efficacy of the device. In addition to achieving this objective, the study will supplement the growing body of knowledge concerning the procedure, assisting physicians with some of its technical aspects, aiding them in selecting candidates most likely to benefit from the procedure, and providing them with comprehensive data to use in comparing this form of therapy for coronary artery disease to the presently available alternatives.

### TECHNICAL APPROACH:

This study will enroll patients who are ASA Physical Status I, and II with Mallampati class I or II airway anatomy and scheduled for elective surgery requiring general anesthesia. Patient selection, risk analysis and specifics are outlined in protocol.

### PROGRESS:

Jul 96: Termination requested. No patients enrolled.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-019 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: Time-Frequency Analysis of Phonocardiograms: A Study of Prosthetic Heart Valve Sounds

START DATE: 12/21/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Moody, J. Mark

ASSOCIATE INVESTIGATOR: Bulgrin, JR; Rubal, BJ; Bauch, TD; Posch, TE

DEPARTMENT/SERVICE: Med/Card FACILITY: BAMC

KEY WORDS: Phonocardiograms (PCG), Prosthetic Heart Valve

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To evaluate an inexpensive, non-invasive method of analyzing phonocardiograms in order to longitudinally assess evolving structural and physiologic problems associated with implanted heart valve prostheses.

### TECHNICAL APPROACH:

This is a descriptive study intended to characterize the time-frequency distributions, via several analytical techniques, of PCGs from as many patients with prosthetic heart valves as possible, and following these patients over a significantly long interval. Further details in protocol.

### PROGRESS:

Sep 96: Dr. Moody reports having trouble developing the system to analyze data. Have received some new equipment and working on it. Want to find gain and frequency of response before enrolling patients.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-022 REPORT DATE: 09/09/96 STATUS: Terminated

TITLE: Time-Frequency Analysis of ECK in Patients Post-Myocardial Infarction and at Risk for Sudden Death

START DATE: 11/01/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Do, Thien M.

ASSOCIATE INVESTIGATOR: Rubal, BJ; Bulgrin, JR; Posch, TE

DEPARTMENT/SERVICE: Med/Cardiology FACILITY: BAMC

KEY WORDS: Post-myocardial infarction, inducible ventricular tachycardia

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 20

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 20

### OBJECTIVES:

To assess the clinical utility of time-frequency analysis of the ECGs in sudden death survivors and patients post myocardial infarction and with inducible ventricular tachycardia.

### TECHNICAL APPROACH:

Inclusion/exclusion criteria, methods for obtaining TFD and signal averaged ECGs, etc. covered in protocol.

### PROGRESS:

Sent to Calif for analysis. Awaiting new software in order to do analysis here.

Nov 95: Study made no progress since last review and was terminated due to lack of funding for necessary equipment.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-027 REPORT DATE: 12/01/95 STATUS: Ongoing

TITLE: Percutaneous Transluminal Coronary Angioplasty Versus Coronary Stenting of De Novo Saphenous Vein Bypass Grafts

START DATE: 12/30/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mego, David

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS: De Novo, saphenous vein bypass grafts, balloon angioplasty

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 6

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

The placement of expandable stents in saphenous vein grafts has shown initial promising results in terms of lower rates of restenosis compared with balloon angioplasty. This is a multicenter, randomized study designed to further examine this subject. Patients with de novo stenoses of saphenous vein grafts will be assigned randomly to either routine angioplasty or the placement of a coronary stent, (supplied by Johnson & Johnson Interventional Systems, Co). Restenosis will be evaluated by routine clinical follow-up, including exercise testing and repeat angiography when indicated. Analysis of angiography and data will be performed by a core lab. BAMC will enroll 15-30 patients, in conjunction with the Univ of Texas Health science Center at San Antonio Cardiology service.

### TECHNICAL APPROACH:

Study population, inclusion/exclusion criteria, materials/methods and further specifics outlined in protocol.

### PROGRESS:

Patients will be premeditated at the discretion of the anesthesiologist. After placement of monitors and preoxygenation, patients will be induced with sufentanil citrate and thiopental sodium or ketamine as indicated by the patient's condition.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-043 REPORT DATE: 02/09/96 STATUS: Completed

TITLE: Comparison of Newer Doppler-Echocardiographic Methods for the Quantification of Mitral Regurgitation

START DATE: 02/04/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Champ, Jerry D.

ASSOCIATE INVESTIGATOR: Mego, David; Rubal, Bernard

DEPARTMENT/SERVICE: Med/Card FACILITY: BAMC

KEY WORDS: Mitral regurgitant volume, control velocity

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 5

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 21

### OBJECTIVES:

To compare the mitral regurgitant volume as determined by three quantitative Doppler techniques: 1) a volumetric method utilizing doppler-derived stroke volume in the left ventricular outflow tract and mitral annulus; 2) a technique involving color flow imaging of the flow convergence region; 3) a new method involving the product of the mitral regurgitant color flow jet area and the mitral regurgitant time velocity integral.

### TECHNICAL APPROACH:

The quantification of mitral regurgitation has been a long-standing problem of some clinical importance. Difficulties in quantifying the regurgitant flow continue despite the advent of Doppler echocardiographic methods for measuring the severity of mitral regurgitation. Several newer techniques have been advanced in the literature addressing this problem. This study compares the accuracy and ease of use of these techniques for calculating regurgitant volume with a volumetric Doppler method in a clinical setting.

### PROGRESS:

Feb 96: Statistical analysis on 21 patients reveals a correlation coefficient for the area method of  $r=0.90$  and that for the flow convergence method of  $r=0.74$ .

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-057      REPORT DATE: 02/01/96      STATUS: Completed  
TITLE: Blood Velocity, Valve Leaflet Flutter and Murmurs in Normal Teenagers

START DATE: 02/14/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Moody, J. Mark

ASSOCIATE INVESTIGATOR: Moody, Andrew T.; Nottestad, Sheri Y; Rubal, Bernard J.

DEPARTMENT/SERVICE: Med/Cardiology      FACILITY: BAMC

KEY WORDS: Valve leaflet flutter, blood flow velocity

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 7

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 7

### OBJECTIVES:

To examine the hypothesis that normal subjects with murmurs are more likely to have valve leaflet flutter than those without murmurs and that these subjects also have higher blood flow velocity than those without murmurs.

### TECHNICAL APPROACH:

Subject population, clinical examination, echocardiographic equipment, data analysis/statistics, etc., outlined in protocol.

### PROGRESS:

Acquired data on seven patients; analysis incomplete, no problems encountered except slow recruiting.

Feb 96: No further patients enrolled, no adverse affects, study completed.

No correlation noted between blood velocity, valve leaflet flutter and murmurs in this small group (<10) patients.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-143      REPORT DATE: 08/01/96      STATUS: Terminated

TITLE: **Thrombus Formation During Coronary Angioplasty in Acute Ischemic Syndromes: Influence of Contrast Media**

START DATE: 09/22/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Mego, David**

ASSOCIATE INVESTIGATOR: Wright, William; Hays, Janet

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 35

### OBJECTIVES:

To determine if contrast media (ionic vs nonionic) impacts on the incidence of thrombus formation during coronary angioplasty in patients with unstable angina pectoris.

### TECHNICAL APPROACH:

The choice of contrast agent may affect the incidence of thrombus formation, acute ischemic complications and costs. This study will help define if ionic or nonionic contrast media should be utilized in patients with unstable isthmic syndromes undergoing coronary angioplasty. Further details outlined in protocol.

### PROGRESS:

Jul 96: This study is now being terminated (Dr. Mego).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-001      REPORT DATE: 09/01/96      STATUS: Ongoing  
TITLE: Stroke Prevention in Atrial Fibrillation III (SPAF III)

START DATE: 10/24/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Boyd, Sheri Y.N.

ASSOCIATE INVESTIGATOR: Modlin, Mego

DEPARTMENT/SERVICE: Med/Cardiology      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 20

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 20

### OBJECTIVES:

1. To compare in a randomized clinical trial the efficacy of adjusted-dose warfarin (INR 2.0 - 3.0) to the combination of low-intensity, fixed-dose warfarin (1-3 mg/day) plus aspirin (325 mg/day), enteric-coated) for the prevention of ischemic strokes and systemic emboli (primary events) in AF patients whose rate of primary events would be predicted to be 6.3%/yr during aspirin therapy. 2. To prove that AF patients without risk factors for thromboembolism have a low rate (<3% per yr) of primary events during aspirin therapy by a longitudinal cohort study.

### TECHNICAL APPROACH:

Specifics are outlined in protocol.

### PROGRESS:

Sep 96: The high-risk recruitment arm was closed due to increased adverse events. the safety monitoring committee however has not closed the low-risk recruitment arm. In the high-risk recruitment patients enrolled at BAMC, no adverse events occurred. All 12 patients in this arm of the study were notified when the study arm closed and returned to their previous therapy for stroke prevention. In the low-risk aspirin arm 8 patients have been enrolled. No adverse events have occurred thus far. Recruitment is ongoing. The goal for recruitment at BAMC is 34 patients during 96, with an overall recruitment goal for the study of 790 patients.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-016      REPORT DATE: 01/01/96      STATUS: Completed

TITLE: Serum CK Response to Endomyocardial Biopsy

START DATE: 01/17/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Malinowski, Timothy R.

ASSOCIATE INVESTIGATOR: Wellford, Armistead; Mego, David; Khan, Nancy; Elmore,  
Phillip

DEPARTMENT/SERVICE: Med/Card      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 10

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

Determine the response of serum total CK and CK isoenzymes following endomyocardial biopsy.

### TECHNICAL APPROACH:

To assist in the assessment of a patient presenting with possible ischemic chest pain following endomyocardial biopsy. Patient selection and further specifics are outlined in protocol.

### PROGRESS:

Jan 96: Protocol is completed.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-048 REPORT DATE: 12/01/95 STATUS: Ongoing

TITLE: A Comparison of Stress Echocardiography, Dobutamine echocardiography, and Adenosine Sestamibi SPECT Perfusion Imaging for Detection of Coronary Artery Disease in Patients with Left Bundle Branch Block

START DATE: 12/19/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Furgerson, James L.

ASSOCIATE INVESTIGATOR: Mego, Bauch, Zimring, Sostre

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To compare stress echocardiography, dobutamine echocardiography, and adenosine SPECT perfusion imaging in the detection of coronary artery disease in identical patients with left bundle branch block by a prospective analysis of all modalities in patients followed at BAMC.

### TECHNICAL APPROACH:

Medical application/status, technical approach and specifics are outlined in protocol.

### PROGRESS:

Dec 95: Charts for prospective study subjects have been reviewed and approximately 20 suitable candidates have been identified.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-057      REPORT DATE: 02/13/96      STATUS: Ongoing

TITLE: Assessment of myocardial viability using the Doppler flo-wire and low dose dobutamine

START DATE: 03/20/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rollefson, William A.

ASSOCIATE INVESTIGATOR: Zimring, Howard; Ebersole, Douglas; Rubal, Bernard

DEPARTMENT/SERVICE: Med/Card      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 8

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 5

### OBJECTIVES:

To assess myocardial viability in patients recently diagnosed with myocardial infarction and resultant left ventricular dysfunction using the Doppler flow wire during low dose dobutamine infusion.

### TECHNICAL APPROACH:

To determine if coronary revascularization at the time of the initial catheterization dysfunction is indicated by using the doppler flo wire and low dose IV dobutamine to predict myocardial viability. By utilizing the Doppler flo-wire to predict myocardial viability the patient will avoid further invasive catheterization procedures, costly viability testing, and several inpatient hospital days.

### PROGRESS:

Feb 96: To date 5 patients have been enrolled to completion with 3 patients being excluded due to fulfilling exclusion criteria. No adverse effects have been observed during the course of the study. Study still ongoing.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-090 REPORT DATE: 02/15/96 STATUS: Ongoing

TITLE: Coronary Blood Flow Hemodynamics in Normal Patients Measured with the Doppler Flo-Wire

START DATE: 02/27/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Zimring, Howard J.

ASSOCIATE INVESTIGATOR: Campos, Ebersole

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 5

### OBJECTIVES:

To obtain normal indices of coronary blood flow velocity, diastolic to systolic velocity ratio, and coronary vascular reserve utilizing the Doppler flo-wire during varying heart rate/blood pressure conditions, and IV dobutamine infusion.

### TECHNICAL APPROACH:

Medical application, status, methods, statistics/data analysis and specifics are outlined in protocol.

### PROGRESS:

Feb 96: No adverse affects encountered. Finished enrolling and compiling data.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-095      REPORT DATE: 02/15/96      STATUS: Ongoing

TITLE: Assessment of myocardial viability using the Doppler flow-wire and Positron Emission Tomography in chronic coronary artery disease patients

START DATE: 03/20/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Zimring, Howard J.

ASSOCIATE INVESTIGATOR: Wright, Walsh, Rubal , Ebersole, Gorman

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

To assess myocardial viability in patients with chronic coronary artery disease and resultant left ventricular dysfunction using the Doppler flow wire during low dose dobutamine infusion and compare Doppler flow wire viability to PET scan results.

### TECHNICAL APPROACH:

To determine if coronary revascularization at the time of catheterization of patients with chronic coronary artery disease and left ventricular (LV) dysfunction is indicated by using the Doppler flow wire and low dose IV dobutamine to predict myocardial viability the patient will avoid costly alternative viability testing and several inpatient hospital days.

### PROGRESS:

Feb 96: Patient accrual has been slow. The 3 patients remain on study. No new data available.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-113      REPORT DATE: 02/08/96      STATUS: Ongoing

TITLE: CARES Study Cardiac Risk Evaluation with Exercise Echocardiography Stress Testing

START DATE:      /      /

ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Boyd, Sheri Y.N.

ASSOCIATE INVESTIGATOR: Gilman

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 5

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 5

### OBJECTIVES:

To evaluate the prognostic value of symptom-limited maximal exercise testing with stress echocardiography in coronary artery disease, specifically in patients with chronic stable angina.

### TECHNICAL APPROACH:

Details are outlined in protocol.

### PROGRESS:

Feb 96: Start date of 6 Mar 95 was delayed due to lack of investigator on site at BAMC. Patient enrollment started in Sep 95. No interim data analysis due to low enrollment numbers. No adverse events thus far.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-120 REPORT DATE: 07/01/96 STATUS: Completed

TITLE: Utility of Digital Acoustic Cardiography for the Evaluation of Heart Murmurs

START DATE: 08/11/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Bauch, Terry D.

ASSOCIATE INVESTIGATOR: Rubal, Bulgrin

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 76

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 76

### OBJECTIVES:

1. Establish criteria to differentiate benign from pathologic murmurs in adults using Digital Acoustic Cardiography (DAC). 2. Determine the accuracy of DAC for the differentiation of such murmurs in both active duty and retiree/dependant populations. 3. Determine the accuracy of DAC for detecting clinically significant changes in stenotic aortic valve jet velocity in adults.

### TECHNICAL APPROACH:

Subjects, methods, data collection, statistical analysis and further specifics are outlined in protocol.

### PROGRESS:

Jul 96: No complications. Data collected and analyzed for 76 patients.

Abstract submitted to American Heart Association for oral presentation.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-130 REPORT DATE: 06/01/96 STATUS: Ongoing

TITLE: A Phase II, Placebo-Controlled Multicenter Study of TLC C-53 as an Adjunct to Thrombolytic Therapy in Patients with Acute Myocardial Infarction

START DATE: 09/05/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mego, David

ASSOCIATE INVESTIGATOR: Nadonna, Miller

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 6

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

To assess the efficacy of TLC 3-53 versus placebo in attaining TIMI (Thrombolysis in Myocardial Infarction) 3 coronary blood flow when given to patients with acute myocardial infarction \*MI) who are to receive tissue-plasminogen activator.

### TECHNICAL APPROACH:

Design, number/type patients, key inclusion/exclusion criteria, and details are given in protocol.

### PROGRESS:

Jun 96: Continuing to actively enroll towards our goal of ten patients.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-004 REPORT DATE: 06/01/96 STATUS: Ongoing

TITLE: **A Randomized, Double-Blind Evaluation of the Efficacy and Safety of two Dosing Regimens of Integrelin Versus Placebo for Reducing Mortality and (Re) Infarction in Patients with Unstable Angina or Non-Q Wave Myocardial Infarction**

START DATE: 11/08/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mego, David M.

ASSOCIATE INVESTIGATOR: Wright, Modlin

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 4

OBJECTIVES:

The coumarin therapy including drug information details, eligibility criteria, descriptive factors,

TECHNICAL APPROACH:

Subjects with type II diabetes with mild to moderate hypertension (defined in protocol) and urinary protein excretion of greater than one gram per twenty-four hours will be enrolled in the study. Age for eligibility will be 45 years or greater.

PROGRESS:

Jun 96: Dr. Mego reports that all 4 patients are doing fine; no complications. Study remains ongoing.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-005

REPORT DATE: 01/05/96

STATUS: Ongoing

TITLE: **Heart Rate Variability as a Predictor of Clinical Response to Beta-adrenergic Blockade in Patients with Idiopathic Dilated Cardiomyopathy**

START DATE: 11/15/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Flaherty, Patrick J.

ASSOCIATE INVESTIGATOR: Mego, Zimring, Rubal, Khan

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

We wish to assess the value of determining baseline ambulatory heart rate variability as a predictor of clinical response to beta-adrenergic blocking agents in patients with idiopathic dilated cardiomyopathy (DCM).

TECHNICAL APPROACH:

The importance of this project will be to demonstrate that erythromycin enhances gastric emptying in patients with anorexia and bulimia nervosa who have delayed gastric emptying.

PROGRESS:

No report available as of this date. Annual review due Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-028      REPORT DATE: 01/29/96      STATUS: Ongoing  
TITLE: Reduced Anticoagulation for Stenting in Native Coronary Arteries

START DATE: 01/08/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mego, David

ASSOCIATE INVESTIGATOR: Steven R. Bailey (UTHSCSA), Thomas A. Carlson

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The efficacy of elective stent placement in reducing restenosis has been demonstrated by recent prospective randomized trials (STRESS and BENESTENT). However, use of stents in these trials was limited by a 3.5% incidence of out-of-lab thrombotic closure and by a 7-14% incidence of hemorrhagic complications. Because of these complications, the role of elective stent use as an anti-restenosis therapy has been questioned. Since the completion of these landmark studies, stent implantation techniques have rapidly evolved. Guided by Columbo's observations using intravascular ultrasound, high pressure expansion has optimized the initial deployment of stents with the potential for reduced subacute thrombosis and improved long-term angiographic results. Results from several observational studies strongly suggest that high pressure inflations and adjunctive use of ticlopidine have reduced the incidence of stent thrombosis and may eliminate the need for anticoagulation with warfarin.

### TECHNICAL APPROACH:

Therefore, we propose to conduct a prospective study of elective implantation of single Palmaz-Schatz stents for new native coronary lesions using current deployment techniques with quantitative coronary angiography follow-up at 6 months. The patient group of this study will be identical in inclusion criteria and exclusion criteria to the STRESS trial and will be analyzed as a nonconcurrent treatment arm of the STRESS trial. It is hypothesized that the "new" stent technique without warfarin will:

To determine whether the use of intravenous perioperative steroids (dexamethasone) enhances the overall recovery in patients undergoing tonsillectomy: (1) by reducing postoperative pain, (2) by reducing postoperative swelling, and/or (3) allowing improved oral intake.ith" warfarin.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-043      REPORT DATE: 01/30/96      STATUS: Ongoing  
TITLE: Stent Anti-thrombotic Regimen Study (STARS)

START DATE: 01/29/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mego, David

ASSOCIATE INVESTIGATOR: Carlson, Thomas A.

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To demonstrate that optimal stent deployment using high pressure balloon inflations followed by treatment consisting of either: 1) aspirin alone or 2) aspirin and ticlopidine, is as safe as optimal stent deployment with aspirin and Coumadin. The exact pre-specified primary endpoint for the trial are enumerated in protocol. Additional efficacy issues will be evaluated by more broadly defined combined 30-day clinical ischemic endpoints including death, Q-wave myocardial infarction, emergent or urgent coronary bypass surgery, repeat PTCA, or subacute thrombosis. The primary endpoint and composite efficacy and safety endpoints will be closely monitored by an independent Data and Safety Monitoring Committee who will define pre-trial stopping rules.

### TECHNICAL APPROACH:

Basic study design, patient enrollment and specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-053      REPORT DATE: 09/01/96      STATUS: Ongoing  
TITLE: **Reduced Anticoagulation After Vein Graft Stenting (RAVES)**

START DATE:      /      /      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: **Ebersole, Douglas G.**

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Card      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

To demonstrate that optimal SVG stent deployment followed by reduced anticoagulation, can be performed safely. The exact prespecified primary endpoints for the RAVES PILOT trial are enumerated in Sec 6.0. The safety issues will be evaluated by comparing the incidence of 30-day major ischemic complications, including death, Q-wave myocardial infarction, emergent or urgent coronary bypass surgery, repeat PTCA or subacute thrombosis. This composite safety endpoint will be closely monitored by the Operations Committee with the intention to stop the trial if untoward complications are realized.

### TECHNICAL APPROACH:

Criteria for eligibility. Patients who warrant revascularization of lesions in native coronary arteries, arterial conduits or more than 2 saphenous vein grafts are not candidates for this trial. Further patient selection, enrollment, study design, etc., outlined in protocol.

### PROGRESS:

One patient with adverse event (IRB notified 17 Jun 96). There was a rupture of the saphenous vein bypass graft. This complication was initially treated and patient had an uncomplicated remainder of his hospital course. Enrollment is now closed; patient follow-up continues.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-067      REPORT DATE: 09/01/96      STATUS: Ongoing  
TITLE: Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM)

START DATE:      /      /      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Gilman, James K.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The Study will compare whether optimized antiarrhythmic drug therapy administered to attempt to maintain sinus rhythm has an impact on total mortality when compared to optimized therapy which merely controls the heart rate. The study will be analyzed by intention-to-treat.

### TECHNICAL APPROACH:

Implementation, Design of Study, and specifics are outlined in study.

### PROGRESS:

No report as of this date. Annual review due Feb 97.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-071      REPORT DATE: 05/21/96      STATUS: Ongoing

TITLE: The Effect of a Prototype Mattress and Arm Positioning Techniques on Musculoskeletal Back and Arm Pain During Invasive Cardiac Procedures

START DATE: 05/22/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Miller, Lois

ASSOCIATE INVESTIGATOR: Ebersole, D; Nottestad, S; Khan, N; Hodge, N

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To test the effect of back and arm support interventions on the patients perception of musculoskeletal pain during invasive cardiac procedures.

### TECHNICAL APPROACH:

The hypothesis, inclusion/exclusion criteria, design and methods and other detailed specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Feb 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-072 REPORT DATE: 05/28/96 STATUS: Ongoing

TITLE: A Pilot Study of Local Delivery of Heparin During PTCA for Acute Myocardial Infarction

START DATE: 05/22/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mego, David

ASSOCIATE INVESTIGATOR: Thomas A. Carlson

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if local infusion of heparin into the coronary wall using the LocalMed Infusasleeve is safe and whether this procedure may allow earlier discontinuation of intravenous heparin.

### TECHNICAL APPROACH:

The study design, hypothesis, device description, patient selection and further specifics are included in protocol.

### PROGRESS:

No report available as of this date. Annual review due Feb 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-081      REPORT DATE: 09/02/96      STATUS: Ongoing  
TITLE: Troponin T as a Non-invasive Marker of Rejection in Heart Transplant Patients

START DATE:      /      /      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Harrington, Kathy

ASSOCIATE INVESTIGATOR: Zimring, Wellford, Horton, Rubal, Khan, Elmore

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess the clinical utility of troponin T as a non-invasive marker of cardiac allograft rejection in heart transplant patients.

### TECHNICAL APPROACH:

Cardiac troponin T is a polypeptide subunit of the myofibrillar regulatory troponin complex that is unique to the cardiac muscle and not normally found in blood. A non-invasive marker of transplant rejection could reduce the frequency of percutaneous right ventricular endomyocardial biopsies in transplant patients. Care of transplant patients would thus be safe and more cost-effective.

### PROGRESS:

No report as of this date. Annual review is due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-111      REPORT DATE: 10/03/96      STATUS: Ongoing

TITLE: Is There a Role for Limited Echocardiography?

START DATE: 08/19/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Edavettal, John M.

ASSOCIATE INVESTIGATOR: Zimring , Boyd, Moody, Rubal

DEPARTMENT/SERVICE: Med/Card

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess the clinical role of performing a limited echocardiogram (instead of a complete study) in a select patient population.

### TECHNICAL APPROACH:

Study patients, exclusionary criteria, data analysis and specifics are outlined in protocol.

### PROGRESS:

Annual review due May 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-88-019      REPORT DATE: 01/01/96      STATUS: Terminated

TITLE: Effect of Oral Agents vs Insulin Therapy on Lipid Profile

START DATE: 01/13/88      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thomason, Albert M.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Endo

FACILITY: BAMC

KEY WORDS: Insulin therapy

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To demonstrate whether low density lipoprotein cholesterol and total cholesterol-high density lipoprotein cholesterol ratios are worse in Type I diabetics treated with insulin as compared to oral agents.

### TECHNICAL APPROACH:

30 patients being treated with oral hypoglycemic agents would be enlisted as volunteers. For the first 3 months, the patient would be followed on his/her usual oral hypoglycemic agent to determine average HGB A1C and lipid profile values. Complete schedule outlined in protocol.

### PROGRESS:

Jan 96: PI is going to retire and no patients are being actively studied at present.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-014      REPORT DATE: 01/01/96      STATUS: Ongoing

TITLE: **Cell Culture Model to Test the Relative Independence of Cancer Cells to Reduced T3 Levels by Comparison to More Normal Cells**

START DATE: 11/04/91      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: **Carlin, Kevin**

ASSOCIATE INVESTIGATOR: Merrill, Gerald, Thomason, Albert, Thompson, Ian; Chapa, Isidoro

DEPARTMENT/SERVICE: Med/Endo

FACILITY: BAMC

KEY WORDS: cell cultures; normal; cancer;

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if reversible hypothyroidism can be induced briefly in euthyroid patients, conceivably normal cells can be induced into a hypometabolic state while the diseased cells continue at their baseline or near baseline metabolic level.

### TECHNICAL APPROACH:

Cell cultures will be grown from prostate tissue recently removed with TURP by urology and documented prostate cancer present by pathological exam.

### PROGRESS:

The data has been written up and submitted for publication which is pending at this time. (Presented in abstract already.)

Nov 95: No change according to Dr. Thomason.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-041      REPORT DATE: 02/08/96      STATUS: Ongoing

TITLE: **Quantification of T3 Receptors in Human Cancer Tissue Compared to The Tissue From the Clear Margin of the Same Surgical Specimen**

START DATE: 12/02/91      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: **Carlin, Kevin**

ASSOCIATE INVESTIGATOR: Merrill, G; Thomason, A; Alvarez, J

DEPARTMENT/SERVICE: Med/Endo

FACILITY: BAMC

KEY WORDS: T3 Receptors; Cancer

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Patients whose medical care has already dictated a surgical procedure for diagnosis and/or therapy of a possible cancer will be considered as a possible candidate to enter the study. There will be no exclusion factors. The only impact to patients for participation is the tissue that was to be removed and will undergo additional analysis.

### TECHNICAL APPROACH:

Patients with known or strongly suspected cancers who are undergoing surgery for diagnosis and/or therapy will have postop examination and testing of a representative sample of their mass and the clear margin. Samples will have their T3 receptors quantified by a previously utilized, well documented method. If the hypothesis is correct, there should be a higher percentage of T3 receptors quantified by a previously utilized, well documented method. If the hypothesis is correct, there should be a higher percentage of T3 receptors in the clear margin than in the cancer cells.

### PROGRESS:

Feb 96: Doctor Merrill of Clinical Investigations confirmed to be having difficulty getting the T3 assay to work.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-085      REPORT DATE: 08/01/96      STATUS: Ongoing

TITLE: Possible Hormone Manipulations in the Treatment of HIV Infections Using Variations in Cell Culture Medium

START DATE: 09/01/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Carlin, Kevin

ASSOCIATE INVESTIGATOR: Kennedy; Anderson; Chapa; Kelly; Merrill; Thomason

DEPARTMENT/SERVICE: Med/Endo

FACILITY: BAMC

KEY WORDS: Hormone; HIV; Cell Culture

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To culture human T cells in a culture medium devoid of human or calf serum.

This will allow full knowledge of what actually is necessary to culture T cells.

### TECHNICAL APPROACH:

Volunteers between ages 18-65 who are not pregnant will donate 10 ml of blood after signing a consent form. This 10 ml of blood will then undergo a process in order to culture normal human T cells. The 10 ml of whole blood will then be spun down to separate red blood cells from white blood cells. The buffy coat containing the white blood cells will then be removed and mononuclear leukocytes obtained via Ficoll-hypaque isopycnic centrifugation.

### PROGRESS:

Aug 95: Dr. Thomason reports that a couple of presentations have been done on this study.

Aug 96: Writing up results and submitting for publication; (to date 5 abstracts, 2 for Endocrine Society and 3 at NIH/CDC HIV meeting). New variation to be addendum.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-098      REPORT DATE: 08/01/96      STATUS: Ongoing  
TITLE: Investigation of a Possible Etiology for Euthyroid Sick Syndrome

START DATE: 05/19/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Carlin, Kevin

ASSOCIATE INVESTIGATOR: Merrill G/Thomason A/Ciceri/Offner/Heironimus/Vaughan

DEPARTMENT/SERVICE: Med/Endo

FACILITY: BAMC

KEY WORDS: Euthyroid Sick Syndrome

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Patients admitted to BAMC who are seriously ill will potentially become candidates in the study. Judgment will be made by TRISS and APACHE III evaluation (an independent established method of objectively scoring patients) within 12 hours of admission to BAMC surgical or medical ICU by the staff physician involved in the study.

### TECHNICAL APPROACH:

Thyroid hormone levels and Triac/Tetrac levels will be tested in ICU patients at admission, as well as at 3 to 4 days and 2 weeks after admission. Subjects will vary as to their primary problem but all will be significantly ill. Analysis will be done to see if their clinical course and thyroid function tests correlate with Triac/Tetrac levels.

### PROGRESS:

95: Dr. Merrill of Clinical Investigation continues to attempt to isolate triac/tetrac.

Aug 96: Dr. Merrill of Clin Inves continues to attempt to isolate triac/tetrac as first step.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-037 REPORT DATE: 02/08/96 STATUS: Ongoing

TITLE: Proposal for a Research Model to Investigate Possible Hormone Manipulations in the Treatment of HIV Infectious Using Variations in Cell Culture Medium to Test for Facilitators and Inhibitors from the Hormone Family (Part II)

START DATE: 03/19/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Carlin, Kevin

ASSOCIATE INVESTIGATOR: Kennedy, Ron; Anderson, Stephanie; Chapa, Isidoro; Merrill, Gerald

DEPARTMENT/SERVICE: Med/Card-Endo FACILITY: BAMC

KEY WORDS: Hormone Manipulations; HIV; Facilitators; Inhibitors

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

HIVs entrance into a cell and subsequent pirating of the intracellular mechanisms bypasses the usual steps in cellular function. HIVs ability to infect cells and/or take over the functions of the cell, may be facilitated and/or inhibited by various hormone levels. If this was found to be true perhaps a hormone manipulation could be designated to enhance therapy.

### TECHNICAL APPROACH:

Fourteen patients under age 60 will be studied. Therapy will follow the schema outlined in the study protocol.

### PROGRESS:

Feb 96: The effects of Triac and Tetrac upon HIV replication invitro was published in abstract for 2nd National Conference Human Retrovirus and Related Infections NIH/CDC meeting 1995. (Dr. Carlin)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-049      REPORT DATE: 02/08/96      STATUS: Ongoing

TITLE: Cell Culture to Test if MCF-7 Breast Cancer Cells in Vitro are Independent of Thyroid Hormone

START DATE: 02/01/94      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Carlin, Kevin

ASSOCIATE INVESTIGATOR: Chapa, I; Thomason, A

DEPARTMENT/SERVICE: Med/IntMed-GMed

FACILITY: BAMC

KEY WORDS: Serum free medium, variable thyroid levels

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

MCF-7 an established breast cancer cell line will be grown in serum free medium with 2 million cells added to each of 4 flasks (as counted by coulter counter). Variable levels of thyroid hormone will be added to each of the 4 flasks. After a period of 10 days the cells will be counted to see if there is a statistically significant difference in the growth rate of the variable thyroid levels.

### TECHNICAL APPROACH:

MCF-7 breast cancer cells will be obtained from an established biological research firm. The cells will be at first grown in their optimum medium for several weeks until sufficient numbers are available. Then two million cells (as counted by coulter counter) will be added to each of four flasks. Serum free medium PFMR-4 from Sigma St Louis will be used as the culture medium. Details given in protocol.

### PROGRESS:

Feb 96: Work on this project was stopped due to PI being sent to Saudi Arabia TDY for 6 months. (Dr. Carlin)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-051 REPORT DATE: 11/01/96 STATUS: Ongoing

TITLE: The Effect of Tetrac and Triac Upon Murine Bladder Cancer Cells in Cell Culture

START DATE: 02/01/94

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Carlin, Kevin

ASSOCIATE INVESTIGATOR: Chapa, I; Thomason, A.

DEPARTMENT/SERVICE: Med/Endo

FACILITY: BAMC

KEY WORDS: Tetrac/Triac, Murine bladder cancer cells, thyroid hormone analogs,

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Murine bladder cancer cells will be grown in serum free medium with 2 million cells added to each of 5 flasks (as counted by coulter counter). Variable levels of Tetrac and Triac (thyroid hormone analogs) will be added to each of the 5 flasks. After a period of 10 days the cells will be counted to see if there is a statistically significant difference in the growth rate with the variable Triac and Tetrac levels.

### TECHNICAL APPROACH:

Murine transitional cell carcinoma (MBT 2) cells were obtained from an in vivo bladder tumor in 1990 and have been maintained in frozen state and cell culture since. Cells have episodically undergone passage thru mice (species Musculus, strain C3H). Two million (as counted by coulter counter) of these cells will be added to each of 5 flasks. Schedule outlined in protocol.

### PROGRESS:

Feb 96: Work on this project was stopped due to PI being sent to Saudi Arabia TDY for 6 months. (Dr. Carlin)

Nov 96: No further work has been done on this study but should be done in near future (Dr. Carlin).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-011      REPORT DATE: 01/01/96      STATUS: Completed  
TITLE: Household Transmission of Hepatitis C Virus in Military Populations.

START DATE: 01/01/92      ESTIMATED COMPLETION DATE: 12/31/95  
PRINCIPAL INVESTIGATOR: Kadakia, Shailesh  
ASSOCIATE INVESTIGATOR: SjogrenMariaH; ShermanKenneth; HoltzmullerKent; MurphyJ  
DEPARTMENT/SERVICE: Med/Gastro      FACILITY: BAMC,  
KEY WORDS: transmission; hepatitis C Virus;  
NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 12  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 50

OBJECTIVES:  
Study will consist of enrolling anti-HCV-positive individuals and anti-HCV-negative individuals with a diagnosis of chronic NANB hepatitis and their household contacts.

TECHNICAL APPROACH:  
Three index cases tested positive for anti-HCV. The serum samples were submitted for further testing to include anti-HCV by ELISA, as well as by RIBA and finally by PCR to detect HCV-RNA. These samples were obtained from 3 index cases and 9 additional household contacts. Total of 56 index patients from BAMC, FAMC, WRAMC, and TAMC have been included in the study with 84 household contacts.

PROGRESS:  
The data has been analyzed in 50 anti HCV positive patients and 83 household members from the four medical centers and US Army Medical Research Inst of Infectious Diseases at Ft Dietrick. Results showed that household exposure to a HCV-infected family member is a risk factor for recording HCV infection, particularly among sexual partners of HCV infected individuals. Jan 96: Paper has been accepted and published in the medical journal Viral Hepatitis and Liver Disease. Study is now complete.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-030

REPORT DATE: 02/01/96

STATUS: Ongoing

TITLE: Regression of Metaplastic Esophageal Epithelium With Omeprazole

START DATE: 02/01/92

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Shaffer, Richard

ASSOCIATE INVESTIGATOR: Kadakia, S ; Carrougher, John

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS: regression; metaplastic response;

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 24

### OBJECTIVES:

To determine if regression of metaplastic esophageal epithelium (Barrett's esophagus) can be induced by utilizing a hydrogen proton pump inhibitor (Omeprazole) to create an achlorhydric environment.

### TECHNICAL APPROACH:

80 patients will be enrolled. Age, sex, duration of disease and prior therapy will be noted for demographic data. Primary exclusion criteria will be due to an indeterminant gastro-esophageal junction by direct endoscopic observation. After complete information outlining the requirements for the study, the current FDA status of Omeprazole and other literature regarding long-term usage of Omeprazole, those subjects declining enrollment in the Omeprazole study group will serve as controls (as they are routinely undergoing annual surveillance). Those meeting endoscopic criteria will be randomized to omeprazole or H2-blockers.

### PROGRESS:

Feb 96: This is an ongoing study and will take approximately 1 yr to complete. To date a total of 24 patients have been enrolled in the study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-094      REPORT DATE: 01/01/96      STATUS: Ongoing

TITLE: Phase II - Colon Carcinogenesis: Modulation by Dietary Intervention

START DATE: 05/01/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Kadakia, Shailesh

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Gastro      FACILITY: BAMC

KEY WORDS: Colon Carcinogenesis; Dietary Intervention

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 41

### OBJECTIVES:

1. To assess the modulation of cellular proliferation in colonic crypts (a biomarker of colon cancer risk) by dietary supplementation with cellulose in patients identified at higher than normal risk of developing malignant colon cancer. 2. To determine if longer term dietary intervention (1 yr or more) of the same supplements will result in a significant reduction in the recurrence of adenomatous polyps in the colon.

### TECHNICAL APPROACH:

Study will be conducted using a prospective randomized control trial. Two dependent variables will be measured: 1) proliferative zone height (PZH), the biomarker previously discussed in the Background and Significance Section and 2) recurrence rate of sporadic adenomatous polyps. The dependent variable, cellulose supplementation will be composed of three levels: 0, 15, and 25 grams/day above normal baseline intake level.

### PROGRESS:

Study design, control, population, patient assignment, dosage administration, etc., outlined in protocol.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-001      REPORT DATE: 09/01/96      STATUS: Ongoing

TITLE: Does Cholecystokinin (CCK) Prevent Gallbladder Sludge or Gallstone Formation in Patients Receiving Parenteral Nutrition

START DATE: 10/14/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Fedalei, Albert

ASSOCIATE INVESTIGATOR: Shah, Rashmikan B.; Wilson, Susan W.

DEPARTMENT/SERVICE: Med/Gastro      FACILITY: BAMC

KEY WORDS: Gallstone Formation; Parenteral Nutrition

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

To compare the efficacy of cholecystokinin in preventing or reducing the incidence of gallbladder sludge and/or cholelithiasis formation in patients receiving total parenteral nutrition (TPN). The incidence of sludge and gallstones formation in the gallbladder will be determined in patients receiving either intravenous cholecystokinin or placebo.

### TECHNICAL APPROACH:

All patients started on TPN will be invited to participate. The presence of gallbladder sludge and gallstone will be evaluated by standard ultrasound technique. Appropriate images will be obtained for each study to record the findings for later review.

### PROGRESS:

Oct 95: To date 3 normal, healthy volunteers have undergone baseline ultrasound study, followed by CCK stimulated study of the gallbladder emptying. Data has not been analyzed because number of patients is very small.

Sep 96: No additional subjects have been enrolled since Oct 95.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-005      REPORT DATE: 02/01/96      STATUS: Ongoing

TITLE: A Comparison Study of Acute Aspirin Induced Gastrodudenal Injury with Omeprazole Versus Misoprostol

START DATE: 08/17/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Shaffer, Richard T.

ASSOCIATE INVESTIGATOR: Carrougher, Greg; Kadakia, Shailesh

DEPARTMENT/SERVICE: Med/Gastro      FACILITY: BAMC

KEY WORDS: Aspirin; Gastroduodenal; Omeprazole; Misoprostol

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 26

### OBJECTIVES:

To compare the effect of omeprazole versus misoprostol in the prevention of aspirin induced gastroduodenal mucosal damage in healthy volunteers.

### TECHNICAL APPROACH:

As outlined in the study protocol.

### PROGRESS:

Feb 96: This is an ongoing study and a total of 26 patients to date have been enrolled. The PI should be changed to Dr. Shaffer from Dr. Timothy Pfanner.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-006      REPORT DATE: 09/01/96      STATUS: Ongoing  
TITLE: Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas

START DATE: 10/01/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Kadakia, Shailesh

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Gastro      FACILITY: BAMC

KEY WORDS: Aspirin;NSAID;Distal Colonic Adenoma

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The purpose of this study is to determine whether a statistically significant difference exists in the prevalence of distal colonic adenomas by fiberoptic flexible sigmoidoscopy (FFS) in a population of aspirin or NSAID users and nonusers.

### TECHNICAL APPROACH:

Patients undergoing a FFS in either the Internal Medicine Clinic at Darnall Army Community Hospital or the Gastroenterology Clinic at BAMC will be eligible for the study. Detailed exclusion data, etc., in protocol.

### PROGRESS:

Oct 95: Biopsy report confirmation ongoing. Data collection on new patients ongoing.

Sep 96: No new patients enrolled. Biopsy report confirmation is ongoing.

This study will become much more active after Nov 96.

(No patient numbers furnished) (Dr. Kadakia)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-008      REPORT DATE: 01/01/96      STATUS: Terminated  
TITLE: Endosonoscopic Evaluation of Helicobacter Pylori Associated Gastritis

START DATE: 11/02/92      ESTIMATED COMPLETION DATE: / /  
PRINCIPAL INVESTIGATOR: Carrougner, John G.  
ASSOCIATE INVESTIGATOR: Kadakia, Shailesh; Shaffer, Richard T.; Redwine, Michael  
DEPARTMENT/SERVICE: Med/Gastro      FACILITY: BAMC  
KEY WORDS: Endosonoscopic; Helicobacter Pylori; Gastritis  
NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:  
To determine if a sonographic pattern can be demonstrate in the gastric mucosa in patients with H.pylori associated gastritis. This information can help define the condition of H pylori gastritis and may assist the physician in the diagnostic difficulties seen with gastric wall abnormalities.

TECHNICAL APPROACH:  
The patient population will include all patients discovered to have H pylori infections as demonstrated by histology and/or urease test (clotest) during routine evaluation by the Gastroenterology Svc. Patients will then undergo endosonography followed by CT scan of the stomach wall. The EUS will be performed by the authors.

PROGRESS:  
Nov 95: No further patients were enrolled since the last reporting period. A total of only 4 patients were enrolled, which was inadequate to provide any meaningful data. Patients were difficult to recruit and the PI has PCSd to Madigan AMC. No other physicians willing to take over study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-012      REPORT DATE: 01/01/96      STATUS: Completed  
TITLE: ASGE Survey: Anticoagulation and GI Endoscopy

START DATE: 11/03/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Angueira, Carlos E.  
ASSOCIATE INVESTIGATOR: Kadakia, Shailesh C.

DEPARTMENT/SERVICE: Med/Gastro      FACILITY: BAMC  
KEY WORDS: Anticoagulation; GI Endoscopy  
NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1269

### OBJECTIVES:

To survey the practices of randomly selected gastroenterologists throughout the country regarding patients on oral anticoagulation or antiplatelet therapy and the way in which these medications should be adjusted prior to and following gastrointestinal endoscopy.

### TECHNICAL APPROACH:

Questionnaires addressing the management of patient on oral anticoagulants, antiplatelet therapy and NSAIDs in the periendoscopy period and strategies in dosage adjustments of these agents will be sent to approx 1200 randomly selected members of the Amer Soc of Gastrointestinal Endoscopy (ASGE) as well as the directors of all the gastroenterology training programs throughout the country.

### PROGRESS:

Nov 95: This study has been completed and a manuscript containing complete findings has been submitted for publication (Dr. Kadakia).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-026      REPORT DATE: 01/01/96      STATUS: Completed

TITLE: Effect of Intravenous Erythromycin on Gastric Emptying in Patients with Anorexia Nervosa or Bulimia

START DATE: 11/02/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Kadakia, Shailesh C.

ASSOCIATE INVESTIGATOR: Katz, Neil; McManis, Susan E.

DEPARTMENT/SERVICE: Med/Gastro      FACILITY: BAMC

KEY WORDS: Intravenous Erythromycin; Gastric; Anorexia Nervosa; Bulimia

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 7

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 7

### OBJECTIVES:

To evaluate the efficacy of intravenous erythromycin on gastric emptying in patients with anorexia nervosa or bulimia. The radionuclide assessed gastric emptying of a standard meal will be performed as baseline in these patients on empty into the study. On a later day, the patients will undergo repeat gastric emptying study 30 minutes after receiving a single dose of 250 mg of intravenous erythromycin. These studies will be compared to the baseline study to determine the beneficial effect of erythromycin on the gastric emptying.

### TECHNICAL APPROACH:

Subject selection, procedures, materials/supplies and specifics are detailed in protocol.

### PROGRESS:

Nov 95: Conclusion: Gastric emptying is significantly improved in patients with anorexia nervosa and bulimia after IV erythromycin. The improvement in gastric emptying after IV erythromycin occurs without significant changes in serum motilin levels. Study is now completed (COL Kadakia).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-043 REPORT DATE: 01/01/96 STATUS: Completed

TITLE: Effects of the Nicotine Patch on Esophageal Motility

START DATE: 01/24/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: DeLaBaume, Henri Renom

ASSOCIATE INVESTIGATOR: Kadakia, Shailesh; Shaffer, Richard T.

DEPARTMENT/SERVICE: Med/Gastro FACILITY: BAMC

KEY WORDS: Nicotine Patch; esophageal Motility

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

To determine if the use of the nicotine patch has any effects on esophageal manometry studies.

### TECHNICAL APPROACH:

A total of 20 volunteers will be enrolled. These will consist of 20 healthy non-smoking adult volunteers. Age and sex will be noted for demographic data. Exclusion criteria will include pregnancy, chronic ETOH use, and any chronic medical conditions requiring medications that cannot be discontinued during the study period. Further details in protocol.

### PROGRESS:

Jan 96: A total of 10 volunteers were entered into the study and the data has been compiled and analyzed. These results have been submitted in manuscript form to a medical journal and awaiting expected publication. CONCLUSIONS: Transdermal delivery of nicotine results in a significant reduction in lower esophageal sphincter pressure without effecting lower esophageal sphincter relaxation or esophageal body motility.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-064      REPORT DATE: 02/08/96      STATUS: Completed

TITLE: Effect of Omeprazole on Blood Alcohol Levels After Oral and Intravenous Ethanol

START DATE: 03/25/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Buckner, Carole A.

ASSOCIATE INVESTIGATOR: Francis, Murray; Kadakia, Shailesh

DEPARTMENT/SERVICE: Med/Gastro      FACILITY: BAMC

KEY WORDS: Omeprazole; Blood Alcohol Levels; Ethanol

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 9

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 9

### OBJECTIVES:

To determine whether or not omeprazole has an effect on blood alcohol levels after oral and intravenous ethanol in normal, healthy volunteers.

### TECHNICAL APPROACH:

Twenty-two male subjects between the ages of 21 and 50 who are eligible for medical care at BAMC will be enrolled. They will be non-smokers and will be social drinkers who consume no more than two liters of beer a week or no more than one drink per day. They will not be on Antabuse or Flagyl, and must not have used any H2-receptor antagonists in the previous 2 weeks. Study will be conducted in four phases as outlined in protocol.

### PROGRESS:

Feb 96: Of the 12 volunteers recruited for this study, 9 subjects completed the study and their data was analyzed. All 9 subjects were males with an age range from 21 to 42 years, mean age of 30 years. The results of this study indicate that, contrary to the reported effects of cimetidine, ranitidine, and nizatidine, omeprazole does not enhance blood alcohol concentrations after administration of intragastric or intravenous alcohol. When treating social drinkers to reduce gastric acid secretion, it is important to select an agent that achieves the desired inhibition without significantly elevating blood ethanol levels. Conclusion: It appears that omeprazole, at least at usual prescribed dosages, does not affect blood ethanol concentration and may be a safer choice than H2-receptor antagonists in treatment the patient needing acid suppression who continues to drink socially.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-044

REPORT DATE: 02/08/96

STATUS: Ongoing

TITLE: **Effect of Intravenous Erythromycin on Gastric Emptying in Patients with Billroth I or Billroth II Anastomosis**

START DATE: 02/01/94

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Kadakia, Shailesh C.

ASSOCIATE INVESTIGATOR: Katz, N; Shah R; Sodhi, V

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS: Erythromycin, Billroth I, Billroth II, anastomosis

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The purpose of this study is to evaluate the efficacy of intravenous erythromycin on gastric emptying in patients with Billroth I and Billroth II anastomosis. The radionuclide assessed gastric emptying of a standard meal will be performed as baseline in these patients on entry into the study. On a later day, the patients will undergo repeat gastric emptying study 30 minutes after receiving a single dose of 250 mg of intravenous erythromycin. These studies will be compared to the baseline study to determine the beneficial effect of erythromycin on the gastric emptying. In addition, serum levels of motilin will be obtained during the baseline gastric emptying study and the gastric emptying study after intravenous erythromycin administration.

### TECHNICAL APPROACH:

All symptomatic adult patients (older than 18 years) who have had previous ulcer surgery wherein billroth I or billroth II anastomosis was performed will be invited to participate in the study. These patients will be evaluated by the staff principal investigator. Patient inclusion/exclusion criteria outlined in protocol. Detailed specifics are outlined in protocol.

### PROGRESS:

Feb 96: There still have been no patients enrolled in this study. Instead of our usual 3 fellows assigned each year, this year only 2 fellows were assigned to the Gastroenterology Service which made their time for research at a premium. Next year, we will again receive our full complement of three fellows and it is hoped that we can begin to enroll patients in this study (COL Kadakia).



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-109      REPORT DATE: 05/01/96      STATUS: Completed  
TITLE: Gastric Hyposecretion in Patients with Walter Reed Stage 6 HIV-1 Infection

START DATE: 06/23/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Farrington, Charles A.

ASSOCIATE INVESTIGATOR: Kadakia, Shailesh; Joyce, Patricia; Schaeffer

DEPARTMENT/SERVICE: Med/Gastro      FACILITY: BAMC

KEY WORDS: Cutaneous anergy, gastric acid secretion, WR-6

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

To investigate a population of WR6 AIDS patients prospectively for incidence of AIDS associated gastric secretory failure, and survey them for incidence of chronic diarrhea so as to determine if the secretory failure is associated with an increased frequency of chronic diarrhea.

### TECHNICAL APPROACH:

Twenty-six subjects with WR Stage 6 AIDS will be required. Ten healthy age-matched control volunteers will serve for comparison of gastric acid secretion between the two groups. Selection of patients for the study will be based on the Walter Reed Staging System for HIV-1 infection. All patients will have clinical AIDS, defined as WR-6. This is defined as being positive for HIV, having a T4 cell count < 400, partial or complete cutaneous anergy, and the presence of opportunistic infections other than thrush. Further details outlined in protocol.

### PROGRESS:

May 96: Total of 6 patients enrolled. Study completed. Pending write up by Dr. Farrington. (Dr. Shaffer)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-129 REPORT DATE: 02/01/96 STATUS: Completed

TITLE: Evaluation of the Clinical and Cost Effectiveness of Therapy with Clarithromycin Plus Omeprazole Compared to Omeprazole or Ranitidine for the Treatment of Patients with Duodenal Ulcer and *Helicobacter pylori* Infection

START DATE: 08/09/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Kadakia, Shailesh

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

The primary objectives of this study are to assess the clinical outcomes and medical costs of treatment with clarithromycin plus omeprazole versus omeprazole alone or ranitidine alone in the treatment of patients with a duodenal ulcer who have a confirmed *H. pylori* infection. The clinical response of the patient will be used as the primary measurement of efficacy. All utilization of medical care related to duodenal ulcer, both direct and indirect, will be collected for the entire study period.

### TECHNICAL APPROACH:

Study design, medical application, plan and further details are outlined in protocol.

### PROGRESS:

Dr. Kadakia requested closure at the Feb IRB meeting.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-017      REPORT DATE: 01/01/96      STATUS: Ongoing

TITLE: Evaluation of the String Test (Enterotest) for Diagnosing Helicobacter Pylori Infection

START DATE: 01/27/95      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Fedalei, Albert G.

ASSOCIATE INVESTIGATOR: Parker, Allan A.

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 35

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 35

### OBJECTIVES:

The purpose of this study is to evaluate the sensitivity and specificity of the Enterotest for diagnosing H. Pylori infection. Optimization of parameters for test administration to maximize sensitivity and specificity will also be evaluated.

### TECHNICAL APPROACH:

All patients undergoing diagnostic endoscopy and antral biopsy for H. pylori will be asked to participate. It is anticipated that approximately 100 subjects will be required to achieve statistical significance.

### PROGRESS:

Jan 96: Excellent, presented at platform William Beaumont symposium at Army ACP meeting 19 Oct 95. Abstract submitted to AGA (Amer Gastroenterological Assn) for presentation at this spring's DDW (Digestive Disease Wk) meeting. No complications to date.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-075      REPORT DATE: 02/20/96      STATUS: Ongoing  
TITLE: **Regression of Barrett's Esophagus After Nissen Fundoplication**

START DATE: 02/27/95      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: **Tanner, Philip E.**

ASSOCIATE INVESTIGATOR: Shaffer, Kadakia, Alvarez, Martin, Root

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This is a prospective study designed to determine if a regression in the length of Barrett's esophagus relative to a tattoo marking occurs after Nissen fundoplication surgery.

### TECHNICAL APPROACH:

The hypothesis to be tested is that the length of Barrett's esophagus regresses or shortens after anti-reflux surgery (Nissen fundoplication). Those patients with endoscopic and biopsy-proven Barrett's esophagus who are referred for Nissen fundoplication will be eligible for the study. Thirty patients will be enrolled.

### PROGRESS:

Feb 96: No enrollment yet; potentially one patient who just had surgery and has signed consent.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-076 REPORT DATE: 02/08/96 STATUS: Completed

TITLE: Concentrations of Methane & Hydrogen in Colonic Gas During Colonoscopy after preparation of the colon with Phospho-soda buffered oral saline laxative solution

START DATE: 02/06/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Pfanner, Timothy P.

ASSOCIATE INVESTIGATOR: Parker, Riel

DEPARTMENT/SERVICE: Med/Gastro FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 13

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 13

### OBJECTIVES:

To measure the concentrations of Hydrogen and Methane in the colon during colonoscopy after the colon is lavaged with Fleets Phospho-soda buffered oral saline laxative. This is to determine if there is any explosive potential during electrocautery in patients who have undergone oral phospho-soda in preparation for colonoscopy.

### TECHNICAL APPROACH:

10-30 patients in whom colonoscopy is indicated and who have utilized Fleet Phospho-soda buffered oral saline laxative solution for colon cleansing will be enrolled into this pilot study. A complete physical examination and clinically indicated lab studies shall be performed by the examining physician.

### PROGRESS:

Feb 96: In 13 patients undergoing colonoscopy utilizing the newer colon cleansing agent, Fleet Phospho-soda buffered oral saline solution, hydrogen and methane levels were measured in the rectum, transverse colon and cecum. All concentrations were well below the minimum combustible levels. The maximum methane level was 0.036% and hydrogen 0.2%. We concluded that concentrations of hydrogen and methane were well below the explosive range in patients using this preparation.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-088      REPORT DATE: 04/01/96      STATUS: Ongoing  
TITLE: Use of Intravenous Erythromycin in Acute Upper Gastrointestinal Hemorrhage

START DATE: 06/05/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Howden, James K.

ASSOCIATE INVESTIGATOR: Kadakia, Fedalai, Farrington, Pfanner, Reil

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 20

### OBJECTIVES:

To investigate the efficacy of intravenous erythromycin, a promotility agent in emptying the stomach and duodenum of blood and clots, to facilitate an adequate endoscopic examination in the acute upper gastrointestinal hemorrhage situation. Erythromycin will be compared to placebo in a study population of all adult patients admitted to the Med Intensive Care Unit with an UGI hemorrhage and oral gastric lavage positive for coffee ground, clots or bright red blood. Patients will be randomized and both patients and physicians will be blinded to the treated and placebo groups.

### TECHNICAL APPROACH:

Outlined in protocol, including experimental design, data collection, statistical analysis, etc.

### PROGRESS:

Apr 96: Still ongoing, need about 30 more patients. No adverse effects.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-096      REPORT DATE: 08/01/96      STATUS: Completed

TITLE: Golytely Bowel Prep - Does Cisapride Help?

START DATE: 06/09/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Tanner, Philip E.

ASSOCIATE INVESTIGATOR: Kadakia

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 75

### OBJECTIVES:

To investigate the use a cisapride as a bowel preparation premedication, to see if it can improve patient tolerance of Golytely, and to see if it improves bowel cleansing.

### TECHNICAL APPROACH:

150 adult patients (age 18-80) undergoing colonoscopy for routinely accepted indications will be randomized in a double-blind manner to a placebo group or a treatment group using 20 mg of cisapride as a premedication prior to golytely bowel lavage. Patients with suspected bowel obstruction will be excluded.

### PROGRESS:

Aug 96: Approximately 75 patients have been entered into the study and from preliminary analysis of the data it appears that Cisapride does assist in the tolerance of the Golytely prep. Statistics are being analyzed and a final manuscript is forthcoming.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-115 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: **Multicenter Trial of Oral Ursodeoxycholic Acid vs Combination Ursodeoxycholic Acid Plus Low Dose Oral Pulse Methotrexate Therapy for Primary Sclerosing Cholangitis**

START DATE: 07/31/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Kadakia, Shailesh C.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To compare ursodeoxycholic acid therapy with low dose oral pulse methotrexate (MTX) combined with UDCA in treatment of primary sclerosing cholangitis. A secondary objective is to describe the course of the disease over 2 years under two different treatment regimens using symptoms questionnaire, laboratory data, histology, and quantitative liver function tests to include quantitative HIDA scan and serum indocyanine green clearance.

### TECHNICAL APPROACH:

Medical application, status, plan, inclusion/exclusion, design of study and further details are covered in protocol.

### PROGRESS:

No report available as of this date. Annual review due Dec 96.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-023      REPORT DATE: 01/01/96      STATUS: Ongoing

TITLE: Aspirin, Nabumetone and Colonic Proliferation

START DATE: 01/02/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Kadakia, Shailesh

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

a. Determine the effects of aspirin and nabumetone on biological intermediate markers of cancer in a population at increased risk of developing colon cancer, namely, patients found to have adenomatous colon polyps, and (b) determine the mechanisms of aspirin and nabumetone by correlating the colonic mucosal prostaglandin levels with proliferation biomarkers.

### TECHNICAL APPROACH:

To determine if kerolac tromethamine is effective in providing pain relief in myofascial pain syndrome, and if so, for how long.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-026 REPORT DATE: 01/29/96 STATUS: Ongoing

TITLE: Effect of Nicotine on Gastric Emptying of Solid and Liquid Contents in Healthy Subjects

START DATE: 12/26/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Wong, Peter W.K.

ASSOCIATE INVESTIGATOR: Kadakia, McBiles

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the serum nicotine levels in subjects treated with nicotine patch. To determine the effect of nicotine patch on gastric emptying of liquid and solid meals in healthy subjects. A dose response graph will then be constructed on nicotine's effect on gastric emptying.

### TECHNICAL APPROACH:

Subjects, design and methods, data collection methods, statistical analysis and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Dec 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-056 REPORT DATE: 03/21/96 STATUS: Ongoing

TITLE: Ursodeoxycholic Acid and Alpha-Interferon Combined Treatment for Chronic Viral Hepatitis Type B and Type C

START DATE: 02/29/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Wong, Peter WK

ASSOCIATE INVESTIGATOR: WRAMC

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC /WRAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

To observe if patients with the diagnosis of chronic hepatitis B or chronic hepatitis C have a more favorable response to alpha-interferon (alpha-INF) when ursodeoxycholic acid is added to the treatment regimen as compared to similar patients who are only treated with alpha-INF. the response will be assessed by biochemical, virological and histological criteria.

TECHNICAL APPROACH:

Status, plan, patient enrollment and detailed specifics are outlined in protocol.

PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-101 REPORT DATE: 07/15/96 STATUS: Ongoing

TITLE: Sublingual Administration of the Anti Spasmodic Agent Levsin as Premedication for Flexible Sigmoidoscopic Examination

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Szykowski, Ronald D.

ASSOCIATE INVESTIGATOR: Fedalei, Kadakia,

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess if flexible sigmoidoscopy can be facilitated by the immediate preprocedure administration of a rapid acting sublingual form of the smooth muscle relaxing agent hyoscyamine sulfate (Levsin).

### TECHNICAL APPROACH:

Hypothesis: The sublingual administration of Levsin SR and Levsin Elixer as pre-medicationf or routine screening flexible sigmoidoscopy will shorten procedure time and decrease patient's subjective discomfort level. Subjects, design/methods and further details are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jul 97

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-102      REPORT DATE: 07/15/96      STATUS: Ongoing  
TITLE: Determination of the frequency of occurrence of Short Segment Barrett's in children and adolescents

START DATE:      /      /      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Szykowski, Ronald D.

ASSOCIATE INVESTIGATOR: O'Connor, Shaffer, Kadakia

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the frequency of occurrence of Short Segment Barrett's Epithelium (SSBE) in children and adolescents.

### TECHNICAL APPROACH:

Hypothesis: This study is being conducted to assess if SSBE is present in the pediatric population.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-103      REPORT DATE: 07/15/96      STATUS: Ongoing

TITLE: **Determination of the frequency of occurrence of Short Segment Barrett's Epithelium by age group and longitudinal follow-up for progression after India Ink tattooing**

START DATE:      /      /      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: **Szykowski, Ronald D.**

ASSOCIATE INVESTIGATOR: **Shaffer, Kadakia**

DEPARTMENT/SERVICE: **Med/Gastro**      FACILITY: **BAMC**

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD:      0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE:      0

### OBJECTIVES:

To determine the frequency of occurrence of Short Segment Barrett's Epithelium (SSBE) in a young population and to conduct longitudinal follow up for progression of these changes.

### TECHNICAL APPROACH:

Hypothesis: SSBE is present at a greater frequency with increasing age and this metaplastic change will progress in patients not receiving antacid therapy at a greater rate than those receiving antacid therapy.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-104 REPORT DATE: 07/15/96 STATUS: Ongoing

TITLE: Determination of the frequency of occurrence of Short Segment Barrett's Epithelium in patients with treated Achalasia

START DATE: 08/09/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Szykowski, Ronald D.

ASSOCIATE INVESTIGATOR: Shaffer, Kadakia

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the frequency of occurrence of Short Segment Barrett's Epithelium (SSBE) in patients with treated Achalasia.

### TECHNICAL APPROACH:

Hypothesis: Short Segment Barrett's Epithelium is present at a greater frequency in patients with treated Achalasia in proportion to decreased LES pressure, increased reflux score, and increased length of time since treatment.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-136 REPORT DATE: 09/23/96 STATUS: Ongoing

TITLE: Optimization of Bowel Preparation with Overnight Magnesium Citrate prior to Flexible Sigmoidoscopy

START DATE: 09/23/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Wong, Peter WK

ASSOCIATE INVESTIGATOR: Hatzigeorgiou C, Harrison S, Parker A

DEPARTMENT/SERVICE: Med/Gastro

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if oral magnesium citrate in addition to two fleet enemas given prior to flexible sigmoidoscopy can 1. Enhance the insertional length of the sigmoidoscope; 2. Enhance the visual clarity of the examination; 3. Lower number of repeat examinations due to inadequate preparation; 4. Lower the duration of the examination.

### TECHNICAL APPROACH:

Inclusion/exclusion criteria, design/methods, statistical analysis and further specifics are outlined in protocol.

### PROGRESS:

No report due until Jun 97.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-072 REPORT DATE: 02/13/96 STATUS: Ongoing

TITLE: Comparison of Cost Effectiveness of Visual Blood Glucose Monitoring and One Touch in An Outpatient Diabetic Clinic: Effects on Glycosylated Hemoglobin

START DATE: 03/25/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Marple, Richard

ASSOCIATE INVESTIGATOR: Bouska, Linore

DEPARTMENT/SERVICE: Med/Gen Med Svc FACILITY: BAMC

KEY WORDS: Glycosylated Hemoglobin, Glucose V

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. Compare patient interpretation of the Glucose V visual blood glucose test with the One Touch mechanized display. 2. To follow patients placed on the Glucose V visual blood glucose test to see if the diabetic control based on glycosylated hemoglobin has worsened. 3. To delineate subgroups of patients that may utilize Glucose V visual blood glucose tests at significant cost savings compared to the One Touch, without harm to overall diabetic control.

### TECHNICAL APPROACH:

Most patients will show significant worsening of glycosylated hemoglobin with Glucose V when compared with One Touch.

### PROGRESS:

Feb 96: This project has been delayed indefinitely due to loss of personnel.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-87-052 REPORT DATE: 04/01/96 STATUS: Ongoing

TITLE: Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma, Using Ex-Vivo Marrow Treatment with 4-Hydroperoxycyclophosphamide (4-HC)

START DATE: 05/13/87 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rick C.

ASSOCIATE INVESTIGATOR: Thomas, Paul; Potter, Al; Zaloznik, Arlene; Reeb, Barbara

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

1. To evaluate autologous marrow rescue after intensive therapy in patients with acute leukemia and lymphoma in second remission or subsequent remission or in early relapse. 2. To study the effects of ex vivo bone marrow purging utilizing 4-HC on malignant cells, marrow stem cells, and relationship to subsequent engraftment times. 3. To study the acute toxic effects of the preparative regimens.

### TECHNICAL APPROACH:

To be eligible for this study, all patients must have a diagnosis of acute leukemia or aggressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission. Therapy will follow the schema outlined in the study protocol.

### PROGRESS:

Apr 96: One patient enrolled for follow-up. No complications.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-87-062      REPORT DATE: 05/01/96      STATUS: Ongoing

TITLE: Autologous Stem Cell Transplant Master Protocol

START DATE: 06/25/87      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rickey

ASSOCIATE INVESTIGATOR: Reeb, Barbara; Pick, Terry

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 31

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 237

### OBJECTIVES:

1. To develop an autologous bone marrow rescue program at BAMC. 2. To participate in research and clinical studies individually as well as part of the SW Oncology Group and Pediatric Oncology Group. 3. To establish a competent marrow rescue service for all eligible DOD patients for present clinical indications and future indications, i.e., radiation exposure.

### TECHNICAL APPROACH:

Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general anesthesia. The marrow will be prepared by accepted methods and frozen for future reinfusion. (This is the master protocol for the autologous bone marrow transplant program.)

### PROGRESS:

May 96: No unusual or adverse effects encountered.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-90-071      REPORT DATE: 05/01/96      STATUS: Ongoing

TITLE: High Dose Chemotherapy with Autologous Bone Marrow Support for Selected Advanced Solid Tumors

START DATE: 06/07/90

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rick C.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 13

### OBJECTIVES:

To determine the toxicity, time to marrow reconstitution, responsive rate, and time to treatment failure of high-dose combination chemotherapy with carboplatin, etoposide, and cyclophosphamide followed by autologous marrow infusion in eligible patients with advanced metastatic solid tumors.

### TECHNICAL APPROACH:

The therapy will follow schema outlined in the study protocol.

### PROGRESS:

May 96: No unusual or adverse effects encountered.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-90-090 REPORT DATE: 07/01/96 STATUS: Ongoing

TITLE: Intensive Therapy and Autologous Bone Marrow Transplant with 4-HC Purging in Acute Myelocytic Leukemia (AML) and Acute Lymphocytic Leukemia (ALL)

START DATE: 08/30/90 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rick C.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 8

### OBJECTIVES:

To determine the effects of autologous transplantations with 4-HC-treated marrow on hematopoietic reconstitution, actuarial relapse rate, and leukemia-free survival in pediatric and adult patients (< 65 y/o) with AML in second or third remission, and ALL in second or third remission.

### TECHNICAL APPROACH:

Fourteen patients under age 60 will be studied. Therapy will follow the schema outlined in the study protocol.

### PROGRESS:

Jul 96: Interim analysis not done yet. No adverse effects. Study ongoing.  
Dr. Myhand is new PI replacing Dr. Vukelja.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-019 REPORT DATE: 02/01/96 STATUS: Ongoing

TITLE: An Open Protocol for the Use of Anagrelin (Anagrelide) for Patients with Thrombocythemia

START DATE: 12/09/92

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Jenkins, Terry R.

ASSOCIATE INVESTIGATOR: Onc staff and fellows

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS: Agrelin; Anagrelide; Thrombocythemia

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

To assess the safety and efficacy of Anagrelide in patients suffering from thrombocythemia of various etiologies.

### TECHNICAL APPROACH:

Inclusion/exclusion criteria; concomitant medications; drug supplies; screening and initial treatment along with other specifics given in protocol.

### PROGRESS:

The one patient enrolled on this study left the military and his care was assumed by the VA Hospital in Temple, TX. Since the last review there were no adverse events and our patient had continued to do well. The study remains open for possible compassionate enrollment of other patients. Effective immediately, Terry R. Jenkins, COL, MC, Asst Chief, Hematology-Oncology Service will become the new PI replacing Timothy ORourke, COL, MC

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-052      REPORT DATE: 10/01/96      STATUS: Completed

TITLE: Gemcitabine as Palliative Therapy in Patients with Progressive Carcinoma of the Pancreas

START DATE: 07/20/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard III

ASSOCIATE INVESTIGATOR: Onc staff and fellows

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/UTHSCSA

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

To assess the clinical benefit of gemcitabine therapy in patients with progressive cancer of the pancreas as measured by significant improvement in pain, performance status, or weight change. Also, to measure time to progressive disease, survival, objective tumor response rates, duration of clinical benefit response, and univariate assessments of the primary variables. To assess differences in the population pharmacokinetics in these patients.

### TECHNICAL APPROACH:

Detailed specifics outlined in protocol.

### PROGRESS:

Oct 96: Study is now completed. The one remaining patient has been taken off study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-083      REPORT DATE: 05/01/96      STATUS: Ongoing

TITLE: High-Dose Taxol, Cyclophosphamide, and Cisplatin (Taxol/CPA/cDDP) with Autologous Bone Marrow Support (ABMS) for Metastatic Breast Cancer

START DATE: 06/10/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rick C.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 12

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 12

### OBJECTIVES:

To determine the toxicity, time to marrow reconstitution, response rate and time to treatment failure of high-dose combination chemotherapy with taxol, cyclophosphamide and cisplatin, followed by autologous marrow infusion in eligible patients with metastatic breast cancer. To provide a new drug in combination with other chemotherapeutic agents in management of individual patients with advanced breast cancer.

### TECHNICAL APPROACH:

Patient eligibility, descriptive factors, treatment plan, etc, outlined in protocol.

### PROGRESS:

May 96: No unusual or adverse effects encountered.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-104 REPORT DATE: 02/09/96 STATUS: Completed

TITLE: Phase I Trial of VP16 + AMGEN rG-CSF in Patients with Advanced Malignancies

START DATE: 07/30/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: O'Rourke, Timothy; Rinaldi, David; Cobb, Patrick

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS: VP16; r-G-CSF; Advanced malignancies

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

To determine the maximally tolerated dose and toxicities of VP16 when combined with r-G-CSF in patients with advanced malignancies. To determine which schedule of administration of r-G-CSF and VP16 is superior in ameliorating toxicity while maximizing potential synergy of the two agents. To determine the recommended dose and schedule of VP16 + r-G-CSF to be used in phase II trials. To document any responses that may occur with this combination.

### TECHNICAL APPROACH:

Design/methods, subject population, recruitment and other specifics outlined in protocol.

### PROGRESS:

Feb 96: Accrual goes well, results are encouraging and anti-tumor activity has been seen. A MTD should be established soon.

Oct 96: Dr. Burris' letter requesting closure presented to IRB.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-117 REPORT DATE: 05/01/96 STATUS: Ongoing

TITLE: A Phase II Study of Gemcitabine in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

START DATE: 08/01/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

To assess the clinical-benefit of intravenous gemcitabine in patients with hormone-refractory prostate cancer (HPRC) as measured by Karnofsky Performance Status (KPS), and pain palliation.

### TECHNICAL APPROACH:

Investigational plan, study population, dosage and administration, concomitant therapy and other specifics covered in protocol.

### PROGRESS:

May 96: Accrual has been difficult due to the very specific inclusion/exclusion criteria, but of date, it has increased activity. The treatment has been well-tolerated overall with moderate myelosuppression. Several patients have experienced clinical benefit. We anticipate closure shortly.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-129 REPORT DATE: 02/09/96 STATUS: Ongoing

TITLE: A Phase II Study of MGBG in Patients with Hormone Refractory Prostate Cancer

START DATE: 09/21/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: Fields, Suzanne; Von Hoff, Daniel; Weiss, Geoffrey;  
Eckardt, John

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

To assess the clinical benefit of intravenous MGBG in patients with hormone refractory prostate cancer (HRPC) as measured by time to disease progression, Karnofsky performance status, and pain palliation. To determine the objective response rate of intravenous MGBG in those patients with HRPC and measurable disease. To evaluate the qualitative and quantitative toxicities of intravenous MGBG in patients with HRPC.

### TECHNICAL APPROACH:

Patient eligibility, treatment plan, drug administration, etc, covered in protocol.

### PROGRESS:

Accrual of patients temporarily halted due to toxicity (mucositis). Enrollment has resumed on a modified dose schedule with pharmacokinetics (PK) being collected.

Feb 96: Accrual completed. Insufficient activity noted to continue to the next stage of enrollment. Well tolerated on the modified dose schedule.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-133      REPORT DATE: 08/01/96      STATUS: Ongoing  
TITLE: A Phase II Trial of RP 56976 in Patients with Cholangiocarcinoma

START DATE: 09/24/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: Cobb, Patrick; Eckardt, John R; Fields, Suzanne; Kalter, Stephen; Kuhn, John

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess whether taxotere given as an every three week intravenous infusion procedures objective clinical responses in patients with cholangiocarcinoma. To assess the clinical and laboratory toxicities as well as patient tolerance of this dose/schedule of intravenous taxotere.

### TECHNICAL APPROACH:

Design, dose regimen, number and selection of patients, and other specifics are outlined in protocol.

### PROGRESS:

Aug 96: Accrual has proceeded steadily (at the other sites, CTRS, Audie Murphy, etc.) with many patients being ineligible because of elevated LFT's. the trial is nearing completion; only minor responses have been seen; toxicities have centered on myelosuppression as expected.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-008 REPORT DATE: 02/09/96 STATUS: Ongoing

TITLE: Elimination of Extrachromosomal DNA from Ovarian Cancer Patients' Tumors with Hydroxyurea Treatment

START DATE: 01/01/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, T; Jenkins, T; Cobb, P; Rinaldi, DA; Heaven, RF

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS: Extrachromosomal DNA, Hydroxyurea, refractory ovarian cancer

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

To determine if hydroxyurea can decrease the amount of extrachromosomal DNA in patients' ovarian cancer cells. To determine if hydroxyurea can decrease the number of ovarian cancer cells in patients' malignant ascites. To determine the amount of transport of hydroxyurea into malignant ascites of patients with ovarian. To determine if hydroxyurea induces responses in patients with advanced refractory ovarian cancer.

### TECHNICAL APPROACH:

Patient eligibility criteria, descriptive factors, treatment plan and detailed specifics are outlined in protocol.

### PROGRESS:

Accrual has been slow but preliminary results are encouraging. Ascites has been ameliorated and extrachromosomal LDNA counts reduced with the use of hydrea. Feb 96: Accrual continues to be slow due to unique patient population, but results remain promising. Enrollment continues.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-023 REPORT DATE: 12/01/95 STATUS: Completed

TITLE: A Phase I Study of AM-285 Administered Via the Intraperitoneal Route in Patients with Intraperitoneal Predominantly Tumoral Disease

START DATE: 12/01/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS: Intraperitoneal route, pharmacokinetic profile

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the safety and tolerance of AM-285 at doses ranging from 10 to 150 mg/kg administered by the intraperitoneal route. To determine the pharmacokinetic profile of AM-285 when administered via this route/schedule.

### TECHNICAL APPROACH:

Patient selection, study synopsis (treatment program), and other specifics included in protocol.

### PROGRESS:

Dec 95: This protocol was delayed indefinitely due to the impracticability of administering the drug in the fashion (intraperitoneally). This study should be considered completed.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-024      REPORT DATE: 08/01/96      STATUS: Completed

TITLE: A Phase I Trial of LY231514 Administered as a Bolus Given Intravenously Every 21 Days

START DATE: 09/01/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rinaldi, David A.

ASSOCIATE INVESTIGATOR: VonHoff, DD; Burris, H; O'Rourke, TJ; Cobb, P; Perez, E;  
et al

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS: Bolus infusion, pharmacokinetics/pharmacodynamics LY231514 cancer

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

To determine the maximum tolerated dose of LY231514 administered as a bolus infusion given every 21 days. To determine the qualitative and quantitative toxicities of LY231514 on this schedule. To determine the recommended dose of LY231514 on this schedule for Phase II trials. To collect info about the antitumor effects of LY231514.

### TECHNICAL APPROACH:

Study population/criteria, dosage administration, efficacy criteria and detailed specifics outlined in protocol.

### PROGRESS:

Aug 96: Accrual completed; manuscript has been written. Objective responses noted in patients with pancreatic and colon cancer. Toxicities were moderate and consisted of neutropenia, thrombocytopenia, dermatitis and mucositis. Phase II trials are underway. This report is final.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-025 REPORT DATE: 08/01/96 STATUS: Completed

TITLE: A Phase I/II Dose-Escalating Study of Intravenously Administered Tirapazamine (WIN 59075) in Combination with Cisplatin, in Patients with Non-Small Cell Lung Cancer

START DATE: 09/01/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: Rodriguez, Gladys

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS: Tirapazimine, Cisplatin, maximum tolerated dose (MTD)

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 4

### OBJECTIVES:

To determine the safety and side effects of tirapazamine, when administered IV in combination with cisplatin, by monitoring patients for adverse effects through clinical observations and laboratory parameters. To determine the pharmacokinetics of tirapazamine and cisplatin, when administered IV in this combination with cisplatin, through periodic sampling of the patients' body fluids. To estimate the maximum tolerated dose (MTD) of tirapazamine, when administered IV in combination with cisplatin, by evaluating all therapy related adverse events.

### TECHNICAL APPROACH:

Study design, inclusion/exclusion criteria, study plan, dosing procedure and specifics outlined in protocol.

### PROGRESS:

Aug 96: Accrual complete, protocol closed, results presented at ASCO 96, and a manuscript is in preparation. The treatment was very effective with a >30% response rate and a 50% 1-yr survival. A randomized phase III trial has been initiated internationally. Toxicities have been manageable with anti-emetics. This report is final.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-036 REPORT DATE: 07/01/96 STATUS: Completed

TITLE: A Phase I Trial of Losoxantrone in Combination with Paclitaxel in Patients with Refractory Malignancies

START DATE: 01/24/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, T; Jenkins, T; Burris, H; Rinaldi, D; Heaven, R.

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC, VA,

KEY WORDS: Losoxantrone, Paclitaxel Dose limiting toxicities (DLTs),

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 6

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

1. To determine the maximum tolerated dose and the recommended dose for subsequent Phase II trials of losoxantrone in combination with paclitaxel. 2. To determine the dose limiting toxicities of losoxantrone in combination with paclitaxel, including qualitative and quantitative toxicities, and to define their duration and reversibility. 3. To evaluate the pharmacokinetics of losoxantrone and paclitaxel when given in combination. 4. To evaluate the antitumor activity of losoxantrone plus paclitaxel. study design, duration, study population, medications, etc., outlined in protocol.

### TECHNICAL APPROACH:

Approximately six months will elapse from the enrollment of the first patient until the enrollment of the last patient. Enrollment will continue until the maximum tolerated dose is identified.

### PROGRESS:

Jul 96: Accrual has been completed and a manuscript is in preparation. A presentation of the study was made at the NCI-EORTC new drug symposium in Amsterdam. The regimen was well tolerated and excellent antitumor activity noted.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-037      REPORT DATE: 06/01/96      STATUS: Terminated  
TITLE: The Effect of h Corticotrophin-Releasing Factor on Peritumoral Brain Edema, A Pilot Study

START DATE: 01/25/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, T; Jenkins, T; Burris, H; Rinald, D; Heaven, R.

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC, UTHSCSA, CTRC

KEY WORDS: h-Corticotrophin-Relating Factor, Peritumoral Brain Edema

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To evaluate the tolerability of h Corticotrophin-releasing factor administered intravenously in ascending doses to patients with peritumoral brain edema. 2. To determine if h corticotropin-releasing factor produces any reduction in peritumoral brain edema as determined by magnetic resonance imaging.

### TECHNICAL APPROACH:

Materials/methods, study population, study design, study plan and management, etc, outlined in protocol.

### PROGRESS:

Jun 96: This protocol requires 2 MRI evaluations of the brain performed within 24 hours of each other and they must be done on the machine at UTHSCSA. This has proven to be technically not feasible (transporting patients with active, newly diagnosed metastases). We will thus withdraw this protocol.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-038 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: Phase 2 Double/Blind, Randomized Study of Recombinant Human Interleukin 11 (NEUMEGA rhIL-11 Growth Factor) at Doses of 25 and 50 mcg/kg/d vs Placebo in Adult Cancer Patients with Severe Thrombocytopenia Due to Chemotherapy

START DATE: 01/27/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, T; Jenkins, T; Cobb, P; Rinaldi, DA; Heaven, RF

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC, VA,

KEY WORDS: rhIL-11 Growth Factor, Placebo, Thrombocytopenia, ameliorating

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To compare the activity of two doses (25 and 50 mcg/kg/d) of recombinant human interleukin 11 (NEUMEGA rhIL-11 Growth Factor) with a placebo in ameliorating severe chemotherapy-induced thrombocytopenia in cancer patients receiving a variety of chemotherapy regimens and to gain additional information regarding the safety of rhIL-11 administration at the specified doses. Also to assess whether IL-11 antibodies are produced and to measure IL-11 serum levels.

### TECHNICAL APPROACH:

Design, eligibility, treatment plan, adverse experiences, statistical analysis, etc, outlined in protocol.

### PROGRESS:

Jan 96: Accrual has gone poorly at all sites. A very specific and difficult to find population is being studied. Attempts at enhancing accrual are being made.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-039 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: Phase I Clinical and Pharmacokinetic Evaluation of LY 295501 Administered Orally on a Weekly Schedule in Patients with Metastatic Cancer

START DATE: 01/27/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, T; Jenkins, T; Cobb, P; Rinaldi, DA; Heaven, RF

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC,

KEY WORDS: Metastatic, maximum tolerated dose, anti-tumor effects

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

Primary objective of this study is to determine the maximum tolerated dose of LY295501 as a single dose given once weekly for 3 weeks every 4 weeks in patients with metastatic cancer. Secondary objectives are to determine the qualitative and quantitative toxicities of LY295501 as a single dose given once weekly for 3 weeks every 4 weeks in patients with metastatic cancer, to determine the recommended dose of LY295501 to be used for initial therapeutic trials, to determine the basic pharmacokinetics of LY295501 by study of plasma and urinary levels of the agent in humans, and to collect information about the antitumor effects of LY295501.

### TECHNICAL APPROACH:

Study design, control, population, patient assignment, dosage administration, etc., outlined in protocol.

### PROGRESS:

Jan 96: Unexpected severe myelosuppression was seen with some of the schedules utilizing this investigational drug. All ongoing trials with LY295501 are thus on hold at this time. IRB notification will occur, with significant consent form changes and amendments, prior to reinitiating any treatment.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-042 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: A Phase I Trial of Paclitaxel; (IVX-T-101) Administered as a Three-Hour Infusion in Patients with Refractory Non-Small Cell Lung Cancer

START DATE: 01/28/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, T.

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC/UTHSCSA,

KEY WORDS: Paclitaxel, non-small cell

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

1. To determine the maximal tolerated dose of paclitaxel given as a 3-hr infusion every 21 days. 2. To determine the qualitative and quantitative toxicities of paclitaxel given as a 3-hr infusion every 21 days. 3. To characterize the pharmacokinetics of paclitaxel administered as a 3-hr infusion. 4. To determine the recommended dose of paclitaxel given as a 3-hr infusion every 21 days to be used in Phase II trials. 5. To collect info about the antitumor effects of paclitaxel in patients with Non-Small Cell Lung Cancer.

### TECHNICAL APPROACH:

Drug info, eligibility criteria, treatment plan, pharmacokinetics, etc., outlined in protocol.

### PROGRESS:

Due to problems in drug manufacturing, this trial was delayed.

Nov 95: This trial is nearing completion at a dose level of 225 mg/m<sup>2</sup> secondary to dose-limiting neutropenia. Several antitumor responses have been observed. The pharmacokinetics reveal appropriate elimination of paclitaxel through hepatic metabolism.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-053      REPORT DATE: 02/13/96      STATUS: Ongoing

TITLE: A Randomized Clinical Trial Evaluating Topical Vitamin E Oil in the Treatment of Chemotherapy Induced Mucositis

START DATE: 02/14/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rick C.

ASSOCIATE INVESTIGATOR: Lew, Vernon; Atkins, Miriam

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS: Vitamin E Oil, Mucositis, high-dose chemotherapy, neoplasms

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 19

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 28

### OBJECTIVES:

To determine by a prospective, randomized controlled trial, the efficacy of Vitamin E in the treatment of mucositis associated with high dose chemotherapy.

### TECHNICAL APPROACH:

High dose chemotherapy with autologous stem cell support has become an increasingly popular approach for the treatment of various neoplasms. It is used commonly in many hematologic malignancies such as AML, ALL and NHL as well as in an investigational role in some solid tumors like breast cancer. The morbidity and mortality associated with this therapy however is considerable and has limited its routine use. Details including drug information, patient eligibility, treatment plan and specifics are outlined in protocol.

### PROGRESS:

Feb 96: Continue collecting data.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-059      REPORT DATE: 01/01/96      STATUS: Ongoing

TITLE: A Phase I Trial of Navelbine in Combination with Estramustine in Patients with Hormone Refractory Prostate Cancer

START DATE: 11/15/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS: Navelbine, Estramustine, Hormone Refractory Prostate CA

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 4

### OBJECTIVES:

To determine the maximally tolerated dose of Navelbine (vinorelbine tartrate) given as short intravenous injection on days 1 and 8 in combination with a fixed dose of estramustine given orally in three divided daily doses on days 1-21 with the regimen repeated every 28 days. To determine the quantitative and qualitative toxicities of the concomitant administration of Navelbine and estramustine. To determine the recommended dose for Navelbine and estramustine on this schedule.

### TECHNICAL APPROACH:

Patient eligibility, study plan and specifics are outlined in protocol.

### PROGRESS:

Feb 96: Accrual goes well with dramatic responses seen to date. Anticipate closure soon.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-064 REPORT DATE: 08/01/96 STATUS: Completed

TITLE: **Double Blind, Parallel Group Exploratory Study Comparing the Efficacy and Safety of topitriol (Topical Calcitriol) with that of Vehicle in the Protection from Chemotherapy Induced Hair Loss, in Patients with Breast Cancer**

START DATE: 09/20/93

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Burris, Howard A. III**

ASSOCIATE INVESTIGATOR: O'Rourke, Timothy; Jenkins, Terry; Cobb, Patrick;  
Rinaldi, David; Heaven, Ralph

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS: Topitriol, hair loss, doxorubicine, cyclophosphamide 5-fluorouracil

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 11

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 11

### OBJECTIVES:

To determine if 7 days of pre-treatment of the scalp with 0.0025% Topitriol leads to clinically significant (> reduction in hair loss) improvement in the alopecia associated with the use of a standard doxorubicin-containing regimen for the therapy of advanced breast cancer (CAF: Cyclophosphamide, Doxorubicin, and 5-Fluorouracil). The secondary objective is to determine if sufficient systemic absorption of Topitriol occurs with this application regimen to alter calcium metabolism in patients with advanced breast cancer.

### TECHNICAL APPROACH:

Experimental design and methods; schedule of assessments/treatments; patient selection criteria and other specifics are outlined in protocol.

### PROGRESS:

Aug 96: Accrual complete, protocol closed, abstract presented at ASCO and a rough draft of the manuscript prepared. The treatment was in effective and was associated with mild scalp irritation. Other formulations are being considered for study. This report is final.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-066 REPORT DATE: 08/01/96 STATUS: Completed

TITLE: An Open Label, Multicenter, Phase I/II, Dose Escalating Tolerance and Safety Study of Glycosylated Recombinant Human Interleukin-6 (r-hIL-6) in Patients Receiving Chemotherapy

START DATE: 12/01/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, Timothy; Jenkins, Terry; Cobb, Patrick;  
Rinaldi, David; Heaven, Ralph

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS: Interleukin-6 (r-hIL-6), myelosuppressive, hematopoietic, attenuated

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

To assess the safety and tolerance of administering repetitive daily subcutaneous doses of r-hIL-6 to patients with solid tumors before and after myelosuppressive chemotherapy. To identify for future clinical testing a safe and recommended dose and/or maximum tolerated dose of r-hIL-6 by means of cohort dose escalations. To perform study-associated laboratory based investigations which will provide insight into the biologic actions of r-hIL-6 in vivo. To evaluate the rate of hematopoietic recovery after myelosuppressive chemotherapy, and to determine any preliminary evidence of efficacy from r-hIL-6 which may be apparent in terms of attenuated thrombocytopenia or accelerated platelet count recovery.

### TECHNICAL APPROACH:

Study design, population, medications, procedures/assessments, etc, are outlined in protocol.

### PROGRESS:

Aug 96: Accrual complete, protocol closed, results being analyzed. the desired platelet rises (thrombocytosis) post-chemotherapy were seen, but the IL-6 was associated with fever, chills, and flu-like symptoms. Future trials are being planned. This report is final.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-068 REPORT DATE: 08/01/96 STATUS: Completed

TITLE: A Phase I/II Study of SDZ PSC 833 with Doxorubicin, Vincristine, Cyclophosphamide and Prednisone in Patients with Refractory or Relapsed Non-Hodgkin's Lymphoma

START DATE: 09/20/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rinaldi, David A.

ASSOCIATE INVESTIGATOR: O'Rourke, Timothy; Jenkins, Terry; Cobb, Patrick;  
Rinaldi, David; Heaven, Ralph

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS: Doxorubicin, vincristine, cyclophosphamide, prednisone, non-Hodgkin's,

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 5

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

To study the safety and tolerability of SDZ PSC 833 in combination with doxorubicin, vincristine, cyclophosphamide and prednisone (P-DVCP). To evaluate the efficacy (i.e., complete response rate and duration disease free and overall survival) of P-DVCP in refractory or relapsed intermediate or high grade non-Hodgkin's lymphoma (NHL). To determine the MTD of P-DVCP. To study the correlation of mdrl gene expression in tumor specimens with clinical response to P-DVCP.

### TECHNICAL APPROACH:

Study population, treatment assignment, medication, visit schedule/evaluation and other specifics are outlined in protocol.

### PROGRESS:

Aug 96: Accrual is complete, protocol closed, and a manuscript in preparation. A maximally tolerated dose was achieved (doxorubicin 15mg/m<sup>2</sup>) based on febrile neutropenia. Phase III trials are being planned. This report is final. Some activity was seen in the refractory population with several complete remission noted.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-069 REPORT DATE: 08/01/96 STATUS: Ongoing

TITLE: Phase II Trial of Taxotere in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

START DATE: 09/20/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, Timothy; Jenkins, Terry; Cobb, Patrick;  
Rinaldi, David; Heaven, Ralph

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS: Taxotere, HRPC, PSA, Karnofsky performance status, pain palliation

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess the antitumor effect of taxotere in patients with hormone refractory prostate cancer (HRPC) as measured by decline in serum prostate specific antigen (PSA). To assess the clinical benefit of intravenous taxotere in patients with HRPC as measured by time to disease progression, Karnofsky performance status, and pain palliation. to determine the objective response rate of intravenous taxotere in those patients with HRPC and measurable disease. To evaluate the qualitative and quantitative toxicities of intravenous taxotere in patients with HRPC.

### TECHNICAL APPROACH:

Patient eligibility, treatment plan, drug administration, and detailed specifics are outlined in protocol.

### PROGRESS:

Aug 96: No accrued patients to this study as we have had higher priority studies involving navelbine and gemcitabine. the VA hospital (Audie Murphy) has been performing the accrual. Activity has been noted and the therapy has been well-tolerated. I anticipate enrolling patients in the near future.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-082      REPORT DATE: 01/01/96      STATUS: Ongoing

TITLE: A Randomized, Double-Blind Study Comparing Megace Plus Hydroxyurea to Megace Plus Placebo in Patients with Advanced Cancer

START DATE: 12/20/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, Timothy; Jenkins, T; Cobb, Patrick; Rinaldi, David; Heaven, Ralph

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS: Megace, Hydroxyurea, placebo

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 4

### OBJECTIVES:

The primary endpoint for this study is to determine whether low dose of hydroxyurea prolongs survival in patients with advanced cancer. To determine the toxicity of low dose hydroxyurea plus megace in patients with advanced cancer. To determine the impact of hydroxyurea on quality of life of patients with advanced cancer.

### TECHNICAL APPROACH:

Background/rationale, drug information, patient eligibility, treatment plan and other specifics are outlined in protocol.

### PROGRESS:

Nov 95: This trial is nearing completion at a dose level of 225 mg/m<sup>2</sup> secondary to dose-limiting neutropenia. Several antitumor responses have been observed. The pharmacokinetics reveal appropriate elimination of paclitaxel through hepatic metabolism.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-085      REPORT DATE: 01/01/96      STATUS: Ongoing  
TITLE: A Phase I Study of Docetaxel (RP56976) and 5-Fluorouracil Combination Chemotherapy in Patients  
with Advanced Solid Tumor

START DATE: 12/20/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, Timothy; Jenkins, T; Cobb, Patrick; Rinaldi,  
David; Heaven, Ralph

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS: Docetaxel, 5-fluorouracil, advanced solid tumors, first-line

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 5

### OBJECTIVES:

Phase I: To determine the maximum tolerated doses (MTD) of docetaxel and 5-FU in combination, when given to patients with advanced solid tumors. Phase II: To determine the efficacy of docetaxel and 5-FU in combination as first line chemotherapy in advanced breast cancer, with evaluation of objective response rate, duration of response, and time to disease progression.

### TECHNICAL APPROACH:

Entry criteria, plan of the study, data analysis and other specifics outlined in protocol.

### PROGRESS:

Jan 96: This trial is nearing completion. Approximately 60 mg/m<sup>2</sup>, 5-FU 300 mg/m<sup>2</sup>) as predicted preclinically. Toxicities focused on myelosuppression and mucositis. Toxicity noted against gastric and lung cancer.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-086      REPORT DATE: 08/01/96      STATUS: Completed  
TITLE: Serum Collection Study on Patients with Active Colon or Breast Cancer

START DATE: 09/20/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, Timothy; Jenkins, T; Cobb, Patrick; Rinaldi,  
David; Heaven, Ralph

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS: Monoclonal antibodies, nuclear matrix proteins (NMP), sera,

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To evaluate monoclonal antibodies for cancer specific nuclear matrix proteins (NMP) utilizing well documented sera from patients with breast or colon cancer. Identify immunoassays capable of detecting breast or colon cancer in human serum.

### TECHNICAL APPROACH:

Eligibility criteria, study design, and detailed specifics are outlined in protocol.

### PROGRESS:

Aug 96: This study was not performed due to difficulty with assay utilized for measuring this protein by the sponsor, as well as problems with methodology and statistical analysis. This trial is closed and this report is final.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-090      REPORT DATE: 01/01/95      STATUS: Completed

TITLE: Cognitions, Depression, Quality of Life, and Will-to-Live in Lung Cancer Patients

START DATE: 04/11/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Moretta, Brenda J.**

ASSOCIATE INVESTIGATOR: Johnson, Jean M PhD; O'Rourke, Timothy

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

Attempt to study the relationships between cognitive appraisals, depression, quality of life, and will-to-live in lung cancer patients.

TECHNICAL APPROACH:

Characteristics of subjects, subject recruitment measures, confidentiality of data, etc, covered in protocol.

PROGRESS:

Mar 96: Data analysis is complete. Currently in progress of writing discussion. Dissertation to be presented in May 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-099 REPORT DATE: 06/01/96 STATUS: Completed

TITLE: A Phase I Study to determine the Maximum Tolerated Dose of Topotecan Following Oral Administration Over 10 to 21 Days in Patients with Malignant Solid Tumors

START DATE: 02/28/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: Cobb, Frank W; Eckhardt, Gail; Heaven, Ralph; Kalter, Stephen; O'Rourke, Timothy

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS: Topotecan, dose levels, antitumor activity

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

To determine the qualitative and quantitative toxicity of Topotecan when given by oral administration over 21 out of every 28 days and to establish an MTD using this schedule. To determine pharmacokinetics and steady state levels achieved after prolonged oral dosing over a range of dose levels and to document any antitumor activity observed using this schedule.

### TECHNICAL APPROACH:

Study population, conduct of the study, study medication, etc, outlined in protocol.

### PROGRESS:

Jun 96: Closed to accrual. Results are being analyzed and a manuscript will be forthcoming.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-112      REPORT DATE: 06/01/96      STATUS: Ongoing  
TITLE: Phase II Study: Treatment of Lymphoma with High-Dose Chemotherapy Consisting of BCNU, Cytosan,  
and VP-16 with Autologous Stem Cell Support

START DATE: 07/06/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rick C.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 26

### OBJECTIVES:

To assess the efficacy of high dose BCNU, VP-17, and cyclophosphamide with autologous hematopoietic stem cell transplantation in the treatment of selected patients with poor-prognosis Hodgkin's disease or high- or intermediate-grade non-Hodgkin's lymphoma.

### TECHNICAL APPROACH:

Eligibility criteria, treatment plan, drug information and detailed specifics are given in protocol.

### PROGRESS:

Jun 96: No adverse events. The PI has changed to Rickey Myhand, MD.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-126 REPORT DATE: 04/01/96 STATUS: Completed

TITLE: A Pilot Study of Docetaxel (RP 56976) in Patients with Paclitaxel-Resistant Advanced Breast Cancer

START DATE: 04/18/94

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A III

ASSOCIATE INVESTIGATOR: O'Rourke, Timothy; Jenkins Terry; Cobb, Patrick; Rinaldi, David; Heaven, Ralph

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

To determine the objective response rate, duration of response, and toxicity of docetaxel in patients with Stage IV paclitaxel-resistant breast cancer. To examine changes in quality of life over time in patients receiving docetaxel and to correlate scores with response and with toxicity frequencies.

### TECHNICAL APPROACH:

Study objectives, patient identification, plan of the study and further details are covered in protocol.

### PROGRESS:

Mar 96: This multi-institutional trial has been completed. Promising antineoplastic activity was observed. Treatment was well-tolerated. A manuscript is in preparation.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-130      REPORT DATE: 07/01/96      STATUS: Completed

TITLE: Spanish Translation and Validation of a Quality of Life Questionnaire

START DATE: 08/11/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Jenkins, Terry R.

ASSOCIATE INVESTIGATOR: Thompson, Ian M.

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 343

### OBJECTIVES:

Cancer and its treatment can affect any one of the following areas of life: physical functioning, emotional functioning; general symptoms; symptoms commonly associated with treatment for breast and prostate cancer; general health and quality of life. It is very important to have a patient's view of how he or she has been feeling during the treatment. This information can help the physician and patient make decisions about the best care for the patient.

### TECHNICAL APPROACH:

Study procedures and further details outlined in protocol.

### PROGRESS:

Jul 96: The total number of prostate cancer patients accrued from the San Antonio sites was 149. BAMC provided 5 bilingual and 90 non-Hispanic white prostate cancer patients.

The total number of breast cancer patients accrued from San Antonio sites was 194. BAMC provided 3 bilingual, two monolingual Spanish and 22 non-Hispanic white breast cancer patients.

We will now begin data analysis and will be providing results as they become available.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-146 REPORT DATE: 02/09/96 STATUS: Ongoing

TITLE: A Phase III Trial of Crisnatol Mesylate vs BCNU in the Consolidative Treatment of Glioblastoma Multiforme

START DATE: 03/03/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, Timothy; Jenkins, Terry; Cobb, Patrick;  
Rinaldi, David; Heaven, Ralph

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. Primary: To determine whether a year of consolidative chemotherapy with crinamol mesylate is superior to a year of consolidative BCNU as measured by time to tumor recurrence in patients with glioblastoma multiforme. 2. Secondary: To determine whether a year of consolidative chemotherapy with crinamol mesylate is superior to a year of consolidative BCNU as measured by overall survival in patients with glioblastoma multiforme. Additional endpoints: To gather information regarding the quality of life in patients receiving consolidative chemotherapy for glioblastoma multiforme and patients receiving consolidative chemotherapy for glioblastoma multiforme and to obtain additional safety and toxicity information on crinamol mesylate.

### TECHNICAL APPROACH:

Detailed information including preclinical studies, clinical trials, drug information, eligibility criteria, etc., included in protocol.

### PROGRESS:

Feb 96: Accrual continues to be slow to this trial because of stringent eligibility criteria. Preliminary results from other centers prove that this design is feasible to complete and attempts at accrual will continue.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-153      REPORT DATE: 01/01/96      STATUS: Completed

TITLE: An Open-Label, Multicenter, Non-Comparative, Study of Topotecan as Single Agent, Second-Line Therapy (Administered Intravenously as Five Daily Doses Every 21 Days) in Patients with Small Cell Lung Cancer

START DATE: 07/25/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To evaluate the response rate, response duration, and survival in patients with advanced small cell lung cancer who are either refractory or potentially sensitive to first-line chemotherapy and are treated with single agent topotecan administered as five daily 30 minute infusions every 21 days.

### TECHNICAL APPROACH:

Study design overview, population, conduct of the study, screening evaluation and other specifics are outlined in protocol.

### PROGRESS:

Nov 95: Study closed as accrual goals have been met. Results are being analyzed and manuscript is forthcoming.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-005 REPORT DATE: 09/01/96 STATUS: Completed

TITLE: A Phase II Pilot Study of the Antiemetic Effectiveness of IV Granisetron in Patients Receiving Preparative High Dose Chemotherapy Prior to Autologous Bone Marrow Transplantation

START DATE: 09/28/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rickey

ASSOCIATE INVESTIGATOR: Stewart, David; Martin, Scott; Vukelja, Svetislava;  
Jenkins, Terry

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 14  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 14

### OBJECTIVES:

1. To assess the efficacy of single daily doses of intravenous granisetron in preventing nausea and emesis in patients receiving highly emetogenic chemotherapy prior to autologous bone marrow transplantation. 2. To assess patient satisfaction with the antiemetic agent.

### TECHNICAL APPROACH:

Study population, study plan, treatment regimen, etc., outlined in protocol.

### PROGRESS:

Oct 95: Due to absence of PI, report will be forthcoming.

Aug 96: Original PI Matthew McCarty has left BAMC by Dr. Myhand reported that study should be listed as completed. No adverse affects; just more nausea in the Granisetron arm of study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-013      REPORT DATE: 01/19/96      STATUS: Ongoing

**TITLE: High-Dose Chemotherapy with or without Total Body Irradiation with Autologous Stem Cell Support and Alpha-Interferon Consolidation in the Treatment of Patients with Non-Hodgkin's Lymphoma with a Poor Prognosis**

START DATE: 12/05/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rick C.

ASSOCIATE INVESTIGATOR: McCarty, Matthew

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To assess the efficacy of fractionated total body irradiation and cyclophosphamide or BCNU, VP-16 and cyclophosphamide with autologous hematopoietic stem cell transplantation in the treatment of selected patients with poor-prognosis, low-grade lymphoma. 2. To assess the feasibility of administration and the therapeutic effect of post-transplant consolidation therapy with alpha interferon in patients who have achieved a complete response to high dose chemo therapy and ASCT. 3. To assess the prognostic value of serial monitoring of bcl-2 and bcl-1 gene rearrangements as markers of residual lymphoma cells.

### TECHNICAL APPROACH:

Eligibility criteria, treatment plan, etc, are outlined in protocol.

### PROGRESS:

Dec 95: One patient placed on study and doing well so far.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-023 REPORT DATE: 08/01/96 STATUS: Ongoing

TITLE: Phase I Trial of Crisnatol Mesylate on an Increasingly Prolonged Continuous Infusion Schedule in Patients with Refractory Malignancies

START DATE: 08/01/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A., III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

To determine the maximally tolerated dose and the recommended dose for subsequent Phase II trials of crisanatol given as a prolonged continuous infusion. To determine dose limiting toxicities of crisanatol, including qualitative and quantitative toxicities, and to define their duration and reversibility. To determine plasma levels which can be achieved and maintained via a continuous infusion. To detect any evidence of antitumor activity.

### TECHNICAL APPROACH:

Chemistry, eligibility criteria, treatment plan and study procedures are outlined in protocol.

### PROGRESS:

Aug 96: Accrual has proceeded slowly due to the complete nature of the study and strict eligibility criteria. Toxicities have centered around neurotoxicity, as expected, but have been reversible and non-cumulative. A maximally tolerated dose should be reached with the next few patients entered.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-024 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: A Phase I Trial of Paclitaxel and Gemcitabine in Patients with Refractory Solid Tumors

START DATE: 08/15/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A., III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

To identify the maximum tolerated doses and the dose limiting toxicities of gemcitabine and paclitaxel when administered in combination to patients with refractory solid malignancies. To determine the qualitative and quantitative toxicities of the gemcitabine/paclitaxel drug combination. to describe any antitumor activity from combination therapy with gemcitabine and paclitaxel.

### TECHNICAL APPROACH:

Drugs, patient eligibility, descriptive factors, treatment-drug administration and specific info given in protocol.

### PROGRESS:

Jan 96: This Phase I study has accrued rapidly. The treatment has been well-tolerated. evidence for anti-tumor activity has been seen against a variety of tumor types. Accrual should be completed soon with this trial.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-025 REPORT DATE: 08/01/96 STATUS: Completed

TITLE: Phase II Evaluation of MGBG in Patient with Refractory or Relapsed Non-Hodgkin's Lymphoma  
Associated with Acquired Immunodeficiency Syndrome

START DATE: 08/15/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A., III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To estimate the response rate, response duration, and clinical benefit for patients with AIDS-related non-Hodgkin's lymphoma (NHL) treated with MGBG who have previously failed one potentially curative regimen for NHL. To define qualitative and quantitative toxicities of MGBG administered to patients with AIDS related NHL.

### TECHNICAL APPROACH:

Drug information, staging/histology criteria, patient eligibility, treatment plan, dosage modification and specifics are outlined in protocol.

### PROGRESS:

Aug 96: This trial has completed accrual and has been presented at the ASCO (Amer Soc of Clin Onc) meeting. A manuscript is in preparation. A 20% response rate was observed with toxicities being mild and reversible. This report is final.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-026 REPORT DATE: 01/01/96 STATUS: Completed

TITLE: A Phase II Study to Evaluate the Combination Chemotherapy Regimen of Irinotecan HCl (CPT-11)  
Plus Cisplatin in Patients with Inoperable Non-Small Cell Lung Cancer (NSCLC)

START DATE: 10/24/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A., III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 50

### OBJECTIVES:

1. Is irinotecan in combination with cisplatin effective in the treatment of your cancer? 2. If your cancer does respond to treatment, how long will the response last and will this treatment prolong your life? 3. What are the side effects of irinotecan in combination with cisplatin and how often do they occur? 4. Does treatment with irinotecan in combination with cisplatin improve your quality of life?

### TECHNICAL APPROACH:

Drug information, patient eligibility, treatment plan, and specifics are outlined in protocol.

### PROGRESS:

Oct 95: The study has completed accrual, and the activity observed was impressive with numerous responses documented. Toxicity was manageable with modest GI toxicity noted. Trial results are being analyzed as this has a multi-institutional trial including a total of 50 patients. A manuscript is in preparation.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-027 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: A Phase I Study of the Pharmacokinetics, Safety and Tolerability of Single and Combination Administration of VX-710 in Patients Receiving Single Agent Therapy with Paclitaxel

START DATE: 10/24/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A., III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 4

### OBJECTIVES:

To determine the safety and tolerability of VX-710 alone and in combination with paclitaxel. to obtain pharmacokinetic information for various doses of VX-710 administered as a 24 hr infusion alone and concurrently with paclitaxel. to achieve whole blood concentrations of VX-710 in the predicted therapeutically effective range and characterize the pharmacokinetics of the single agent and combination therapy at these doses. To document any antitumor efficacy of VX-710 in combination with paclitaxel.

### TECHNICAL APPROACH:

Design, dose regimen, number and selection of patients, and other specifics are outlined in protocol.

### PROGRESS:

Jan 96: This study has recently been initiated. No unexpected toxicities to date. Accrual is going well.

Sep 96: The study is progressing as expected. Three more patients are expected to be enrolled to verify a maximally tolerated dose. There have been no unexpected toxicities noted to date.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-028      REPORT DATE: 01/01/96      STATUS: Ongoing

TITLE: A Phase I Escalating-Dose Study to Evaluate the Safety and Pharmacokinetics of a Five-day Regimen of Intravenous 1843U89 Alone and in Combination with High-Dose Oral Folic Acid

START DATE: 11/21/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A III

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Cobb, Rinaldi, Atkins

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 6

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

1. To determine the maximum tolerated dose of five daily doses of intravenous 1843U89 when administered alone and in combination with oral folic acid. 2. To evaluate the safety and describe the toxicity of intravenous 1843U89 alone. 3. To evaluate the safety and describe the toxicity of intravenous 1843U89 and oral folic acid when administered together. 4. To determine the pharmacokinetics of intravenous 1843U89 alone. 5. To determine the pharmacokinetics of intravenous 1843U89 and oral folic acid when administered together.

### TECHNICAL APPROACH:

Study design, drugs/dosage info, trial subject selection, etc., are included in protocol.

### PROGRESS:

Nov 95: Initial accrual to the Phase I 1843 portion of the study is complete with mucosins and dermatitis being the dose-limiting toxicity. Escalation is now proceeding with the addition of folic acid, and thus far, the folic acid has ameliorated the toxicities. Hints of activity have been observed in patients with gastric and colon cancer.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-029 REPORT DATE: 09/18/96 STATUS: Ongoing

TITLE: A Phase I Study to Determine the Safety of LU 103793 as a 5-Min IV Infusion, Daily x 5, Given Every 3 Weeks to Patients with Malignant Solid Tumors

START DATE: 10/24/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rinaldi, David A.

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Cobb, Burris, Atkins

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

1. To determine the maximum tolerated dose of LU 103793 when administered as a single 5-min IV infusion daily x 5, given every 3 weeks in adult patients with solid tumors; 2. To determine the qualitative and quantitative toxic effects of LU 103793 and to study the predictability, duration, intensity, onset and reversibility of the toxic side effects; 3. To propose a safe dose (ie. near MTD) for phase II evaluation; 4. To study the pharmacokinetics of LU 103793 in man at the different dose levels, and to evaluate the rationale for this schedule; 5. To document any possible antitumor activity.

### TECHNICAL APPROACH:

This is a mono-center, non-randomized, open-label, uncontrolled dose-finding study. Study population, treatment plan/methods, efficacy and safety parameters, study materials and other specifics are outlined in protocol.

### PROGRESS:

Aug 96: Dose limiting toxicity has been reached and centers on neutropenia. Future plans include stratification for heavily versus lightly pretreated patients. Two cases of drug related hyperbilirubinemia has been noted at other sites. An amendment has been placed to escalate with G-CSF if the hyperbilirubinemic does not become dose limiting.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-030 REPORT DATE: 01/01/96 STATUS: Completed

TITLE: A Phase II Study to Evaluate Alternating Cycles of Irinotecan HCl (CPT-11) and 5-Fluorouracil (5-FU) Plus Leucovorin (LV) in Patients with Metastatic Colorectal Cancer

START DATE: 11/21/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

1. To estimate the antitumor activity of alternating cycles of irinotecan (CPT-11) and 5-fluorouracil plus leucovorin (5-FU/LV) in patients with metastatic colorectal cancer who have not received any prior chemotherapy or radiation therapy for their colorectal cancer. 2. To estimate the duration of response, time to treatment failure, and overall survival in this group of patients. 3. To evaluate the qualitative and quantitative toxicities of this drug combination in patients with metastatic colorectal cancer. Etc.

### TECHNICAL APPROACH:

Eligibility criteria, treatment plan, dosage modifications and other specifics are outlined in protocol.

### PROGRESS:

Jan 96: Accrual has gone well, and substantial antitumor activity has been seen against metastatic colon Ca. Toxicities (diarrhea and neutropenia) have been surprisingly mild. This study is nearing completion.

May 96: Completed. There were three patients registered at BAMC with no adverse events recorded. Results are being analyzed and a manuscript is forthcoming.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-038 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: Phase I Trial to Determine the Maximum Tolerated Dose of Irinotecan Hydrochloride (CPT-11) Using an Every-Other-Week Dosing Schedule in Patients with Advanced Solid Tumor Malignancies

START DATE: 12/19/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Cobb, Rinaldi, Atkins

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 4

### OBJECTIVES:

1. To determine the maximum tolerated dose of irinotecan when administered every other week to patients with advanced solid tumor malignancies. If neutropenia is the dose-limiting toxicity, a new MTD will be determined with concomitant granulocyte colony stimulating factor (G-CSF). 2. To evaluate the qualitative and quantitative toxicities of irinotecan on an every-other-week schedule in this patient population. 3. To obtain a pharmacokinetic profile of irinotecan and its active metabolite, SN-38 at the doses used on an every-other-week schedule.

### TECHNICAL APPROACH:

Drug info, eligibility criteria, pretreatment evaluation, treatment plan, dosage modifications and other specifics are outlined in protocol.

### PROGRESS:

Dec 95: Accrual has proceeded. diarrhea remains the major toxicity of CPT-11 but 6 manageable with immodium. Significant antitumor activity has been observed in patients with refractory colon cancer.

Jan 96: This study has proceeded without problems. Toxicities have centered on myelosuppression and diarrhea, but have been easily managed. Antitumor activity has been noted against colon and lung cancer.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-039 REPORT DATE: 06/13/95 STATUS: Completed

TITLE: A Phase I/II Trial of 5-Ethynyluracil (776C85) Plus 5-Fluorouracil in Patients with Solid Tumors

START DATE: 04/18/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 9

### OBJECTIVES:

To determine the safety of 776C85 (alone) and the lowest dose of 776C85 which effectively inhibits uracil reductase as defined in section 5.4.1. To determine if the pharmacokinetics of 5-FU in 776C85-treated patients allows five-day treatment. to determine the MTD of 5-FU when co-administered with 776C85. To determine the MTD of 5-FU + leucovorin when co-administered with 776C85, after the MTD of 5-FU in the presence of 7876C85 is reached. To determine the pharmacokinetics of 776C85 with and without 5-FU. To determine the pharmacokinetics of 5-FU in combination with 776C5.

### TECHNICAL APPROACH:

Inclusion/exclusion criteria, treatment plan and specifics are outlined in protocol.

### PROGRESS:

Apr 96: The initial portion of this trial was completed successfully and a MTD was determined of 5-FU 25 mg/m<sup>2</sup> with leucovorin, or 30 mg/m<sup>2</sup> alone, in combination with a 776C85 dose of 10 mg. Toxicities included neutropenia and diarrhea as expected. Antitumor activity was noted in patients with colon, gastric and breast cancer. An amendment has been submitted to explore higher doses of 776 (for complete blockade of uracil reductase).

23 Sep 96: Dr. Burris notified the IRB of study completion.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-046 REPORT DATE: 06/01/96 STATUS: Completed

TITLE: Chemoimmunotherapy of Metastatic Renal Cell Carcinoma with Interleukin-2, Interferon- $\alpha$ 2B, and 5-Fluorouracil (#IS-L2001)

START DATE: 12/19/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: Cobb, O'Rourke

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To evaluate the incidence and severity of adverse events occurring during therapy. Evaluate the complete and partial remission rate. Secondary Objectives: Evaluate the durability of the complete and partial responses. Evaluate the progression-free survival in all patients. Evaluate survival in all patients treated.

### TECHNICAL APPROACH:

Study design, patient selection, inclusion/exclusion criteria and other specifics are outlined in protocol.

### PROGRESS:

Dec 95: Accrual goes well in this multi-institutional trial. Several anti-tumor responses have been documented. Toxicity is significant as expected but is manageable, consisting predominantly of flu-like symptoms. Accrual has been proceeding in this multi-institutional trial, and closure is anticipated soon.

Jun 96: Closed to accrual. Results are being analyzed and a manuscript will be forthcoming.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-071 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: A Phase I Study to Evaluate Orally-Administered Irinotecan HC1 (CPT-11) Given Daily x 5 Every 3 Weeks in Patients with Refractory Malignancies

START DATE: 01/30/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR: Cobb, O'Rourke, Rinaldi

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

1. To determine the maximally-tolerated dose and the dose-limiting toxicity of irinotecan when administered orally, once a day for five consecutive days. 2. To characterize the safety profile of irinotecan when administered orally in this manner. 3. to characterize the single and multiple dose pharmacokinetics of irinotecan and its active metabolite, SN-38. 4. To detect any evidence of antitumor activity.

### TECHNICAL APPROACH:

See protocol.

### PROGRESS:

Jan 96: In this study to evaluate the oral tolerability of CPT-11, accrual has proceeded rapidly. Toxicities have been mild and centered predominantly on nausea/vomiting, diarrhea and myelosuppression. Prophylactics are being given to all patients.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-093      REPORT DATE: 01/01/96      STATUS: Ongoing

TITLE: Phase I Trial of Gemcitabine Plus Hydroxyurea in Patients with Refractory Solid Tumors

START DATE: 12/19/94

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 6

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

Primary objective is to determine the MTD and DLT of gemcitabine and hydroxyurea combination therapy when administered to patients with refractory solid tumors. Secondary objectives are: 1. To determine the qualitative and quantitative toxicities of the gemcitabine and hydroxyurea combination therapy. 2. to describe any antitumor activity from gemcitabine and hydroxyurea combination therapy. 3. To measure the activity of the enzyme ribonucleotide reductase in tumor cells of patients receiving gemcitabine and hydroxyurea combination therapy. 4. To measure the pharmacokinetic parameters of gemcitabine and hydroxyurea.

### TECHNICAL APPROACH:

Details outlined in protocol.

### PROGRESS:

Dec 95: This trial is nearing completion and has gone well. Toxicities are predominantly brief myelosuppression, neutropenia and thrombocytopenia. Hints of toxicity have been observed in patients with lung cancer and pancreatic cancer.

Jan 96: Severe myelosuppression has been seen with doses lower than anticipated. Accrual will be completed soon.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-099 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: A Multicenter Randomized Phase III Study of Docetaxel (RP 56976, Taxotere) versus Best Supportive Care in Patients with Non-Small Cell Lung Cancer Previously Treated with Platinum-Based Chemotherapy

START DATE: 02/27/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Primary: To evaluate survival in patients with non-small cell lung cancer previously treated with platinum-containing chemotherapy receiving either docetaxel or best supportive care. Secondary: To compare the quality of life of patients in each treatment arm, and determine the safety and efficacy (response rate, response duration) of docetaxel administered as an one-hr IV infusion every 21 days in a randomized setting.

### TECHNICAL APPROACH:

Detailed specifics are outlined in protocol.

### PROGRESS:

Jan 96: Accrual has proceeded slowly because of the difficulty in a "placebo" or "best supportive care" arm. The number of institutions participating in the study has been expanded to improve the situation.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-100 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: A Phase I Trial and Pharmacokinetic Study of the Sequential Administration of Carmustine (BCNU) and Temozolomide in Patients with Advanced Refractory Solid Tumors or Refractory Lymphoma

START DATE: 05/24/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/WHAFMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

To estimate the maximum tolerated dosage and the dosage for Phase II trials for oral temozolomide in combination with BCNU in patients with advanced cancer and lymphoma. To characterize the dose-limiting toxicity and other toxicities of this combination when either temozolomide or BCNU is given first. To characterize the pharmacokinetics of temozolomide and MTIC on these schedules. to identify any preliminary evidence of anticancer activity in treated patients. to determine ATase levels in mononuclear cells in patients treated on these schedules.

### TECHNICAL APPROACH:

Detailed specifics are outlined in protocol.

### PROGRESS:

Jan 96: Accrual has begun to this trial and no unexpected toxicities have been seen todate. Protocol enrollment continues.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-108 REPORT DATE: 02/08/96 STATUS: Completed

TITLE: Treatment IND of Gemzar (Gemcitabine) for Patients with Pancreatic Cancer

START DATE: 03/20/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Cobb, Burris, Atkins

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 4

### OBJECTIVES:

Primary: To provide for the treatment of patients with locally advanced (Stage IIC or III) or metastatic (Stage IV) pancreatic cancer. Patient access to gemzar through the Treatment IND will occur while the FDA reviews the safety and efficacy as described in the New Drug Application for Gemzar and considers the drug for commercial release. Secondary: To collect further basic safety and efficacy data.

### TECHNICAL APPROACH:

Detailed specifics are outlined in protocol.

### PROGRESS:

Feb 96: Four patients have been treated with Gemzar on this treatment IND. Two patients have been removed from the study for tumor progression and 2 patients are still being treated. Gemzar has been well tolerated. Two adverse events occurred and were reported to the IRB. However, neither event was felt to be drug related. Patient accrual is continuing at this time.  
IRB, 23 Sep 96: Dr. Burris requested study be closed.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-110 REPORT DATE: 04/01/96 STATUS: Ongoing

TITLE: An Open-Label, Multicenter, Randomized, Ph III Study of Hycamtin (Topotecan) as Single Agent, 2nd-Line Therapy (Admin IV as 5 Daily Doses Every 21 Days) Vs 2nd-Line CAV in Patients w/SCLC Who Have Relapsed at Least 3 Mos After Completion of 1st Ln Ther

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Atkins, Yvette

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Cobb, Rinaldi, Burris

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS: Hycamtin

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

To evaluate the response rate and response duration in patient with local or extensive small cell lung cancer who relapsed at least three months after completion of prior chemotherapy, following treatment with single agent Hycamtin administered as five daily 30-min infusions every 21 days, or with a combination of cyclophosphamide, doxorubicin and vincristine administered once every 21 days. Secondary: To eval the time to response, time to progression, survival and symptoms of disease in patients with local or extensive SCLC treated with Hycamtin or with CAV administered on these schedules. To evaluate the qualitative and quantitative toxicities of Hycamtin and of CAV administered on these schedules.

### TECHNICAL APPROACH:

Details are outlined in protocol.

### PROGRESS:

Apr 96: No adverse events; the one patient got randomized thru the CAV and didn't get drug.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-118 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: A Phase I Study of NSC 655649 Given by Bolus Infusion Every 21 Days

START DATE: 07/31/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

1. To evaluate the qualitative and quantitative toxicities of NSC 655649 when administered as a bolus infusion every 21 days. 2. To characterize the pharmacokinetic parameters of NSC 655649. 3. To assess any antitumor effects which might be observed in this initial trial of NSC 655649 in patients with refractory malignancies.

### TECHNICAL APPROACH:

Experimental design/methods; subject population; recruitment/consent procedures and further specifics are outlined in protocol.

### PROGRESS:

Oct 95: This trial has not yet begun accrual as drug availability was a problem. A supply has now been delivered and I anticipate accrual beginning this month (10/95).

Jan 96: This has just opened due to prior problems with drug availability.

Sep 96: Accrual has proceeded well with this trial. A total of 6 dose levels have been replaced with only brief, reversible myelosuppression observed.

Hints of activity have been observed in patients with renal cell cancer. Dose escalation continues. No publications/abstracts to date.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-122 REPORT DATE: 07/01/96 STATUS: Ongoing

TITLE: Letrozole (CGS 20267) Comparison of Two doses (0.5mg and 2.5mg) of Letrozole (CGS 20267) Vs  
Megestrol Acetate in Postmenopausal Women with Advanced Breast Cancer - Protocol 02

START DATE: 08/08/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Atkins, Miriam Y.

ASSOCIATE INVESTIGATOR: Stephenson, Joseph

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

To compare the anti-tumor efficacy, as evaluated by the primary variable of objective response rate, and the secondary variables of duration of response, time to treatment failure (TTF), time to progression (TTP) and time to death among the three treatment arms.

### TECHNICAL APPROACH:

As outlined in the protocol.

### PROGRESS:

Jul 96: Two patients were treated for greater than 6 months; 1 CR, 1 PR. The third patient continues on treatment and is stable. Too early to evaluate. Ongoing.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-124      REPORT DATE: 01/01/96      STATUS: Ongoing  
TITLE: Phase I Trial of Pivaloyloxymethylbuyrate (AN-9) as a 6 Hr Continuous Infusion Daily for 5 Days

START DATE: 08/14/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Aylesworth, Cheryl A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Primary: To determine the maximum tolerated dose of AN-9 when administered as a 6 hr continuous infusion daily for 5 days. The modified continual reassessment method for dose escalation will be employed. The maximum dose will be 3.90g/m<sup>2</sup>/6hr. To determine the qualitative and quantitative toxicities and reversibility of toxicities from AN-9 administered in this fashion.

### TECHNICAL APPROACH:

Specifics are outlined in protocol.

### PROGRESS:

Jan 96: The study has recently been initiated and no toxicity has been seen with the opening dose level. Accrual will be continued per protocol.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-125 REPORT DATE: 05/01/96 STATUS: Terminated

TITLE: A Dbl-Blind, Randomized, Phase 3, Multicenter Study of Suramin and Hydrocortisone vs  
Hydrocortisone and Placebo in the Treatment of Patients with Metastatic, Hormone Refractory Prostate  
CA (Stage D2) (Protocol 1003-01)

START DATE: 08/14/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: O'Rourke, Timothy

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. Determine suramin's effect on pain, performance status, PSA, disease response, quality of life and survival in patients with hormone-refractory prostate carcinoma (2) To evaluate the safety of suramin.

### TECHNICAL APPROACH:

Detailed specifics are outlined in protocol.

### PROGRESS:

May 96: Protocol has been withdrawn by the sponsor due to problems with patient accrual. There were no patients registered to this study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-136      REPORT DATE: 08/01/96      STATUS: Completed  
TITLE: A Phase II Study to Evaluate a 5-Day Regimen of Oral 5-Fluorouracil (5FU) Plus 77685 Colon

START DATE: 09/26/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Cobb, Patrick W.

ASSOCIATE INVESTIGATOR: Cobb, O'Rourke

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

1. To evaluate the safety and efficacy of 5-day oral 5-FU given in combination with 776C85 with or without leucovorin in the treatment of patients with previously untreated metastatic colorectal cancer. 2. To evaluate the safety and efficacy of 5-day oral 5-FU and 776C85 with or without leucovorin in the treatment of patients with metastatic colorectal cancer refractory to 5-FU plus leucovorin. Etc.

### TECHNICAL APPROACH:

Further specifics are outlined in the protocol.

### PROGRESS:

Aug 96: Accrual has proceeded very rapidly to this phase II study. Some of the 6 stratification groups are completed. The trial should be closed in the near future. Objective responses have been seen. Toxicities have included neutropenia, diarrhea and mucositis but have been generally well-tolerated.  
Oct 96: Letter requesting closure presented at IRB meeting.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-141 REPORT DATE: 07/01/96 STATUS: Ongoing

TITLE: Autologous Granulocyte Infusions as Supportive Therapy in Breast Cancer Patients Receiving High Dose Chemotherapy with Stem Cell Support

START DATE: 09/01/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rick

ASSOCIATE INVESTIGATOR: Stephenson, Vukelja, Merrill, Wortham, Martin, Miller

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 10

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

Metastatic breast cancer is an incurable disease. Although systemic chemotherapy and hormonal therapy may prolong survival and palliate symptoms for years, most patients with metastatic breast cancer will eventually die of their illness. recent efforts to improve upon survival using high dose chemotherapy with autologous stem cell support have been widely published and applied. Despite recent advances in supportive care with the use of blood product is still infection. During the period of obligate neutropenia after high dose chemotherapy, virtually all patients suffer from fever necessitating the use of broad spectrum antibiotics.

### TECHNICAL APPROACH:

Further specifics are outlined in protocol.

### PROGRESS:

Jul 96: Preliminary analysis indicates subjective benefit of patient feelings of well-being in all patients. Study remains ongoing.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-007 REPORT DATE: 07/01/96 STATUS: Completed

TITLE: Repeat Oral Dose, Dose-Rising Study of the Safety, Tolerability, Pharmacokinetics and Pharmacologic Effect of SK&F 107647 in Patients with Solid Tumor Malignancies

START DATE: 11/22/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: CTRC

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To assess the safety and tolerability of SK&F 107647 in patients with solid tumor malignancies following repetitive oral dosing for 10 days with 10, 100 and 1,000 ng/kg. 2. To provide preliminary pharmacokinetic data following a single dose and 10 days of repeat oral dosing of SK&F 107647 at 100 and 1000 ng/kg (pre-chemotherapy dosing phase only). 3. To assess hematopoietic synergistic factor (NSF) biologic activity, cytokine (M-CSF) and flow cytometry (CD11b/CD18,CD64) following single and repetitive oral doses of SK&F 107647.

### TECHNICAL APPROACH:

Study plan, design, population, conduct of the study plan, and further specifics are outlined in protocol.

### PROGRESS:

Jun 96: Closed to accrual. The results are being analyzed and a manuscript will be forthcoming.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-008      REPORT DATE: 09/01/96      STATUS: Completed  
TITLE: A Phase 2 Trial of LY231514 Administered Intravenously Every 21 Days in Patients with Pancreatic Cancer

START DATE: 11/22/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: CTRC

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

The primary objective is to determine the response rate for patients with metastatic colorectal cancer who have been treated with LY231514.

### TECHNICAL APPROACH:

Summary of study design, discussion of design and control, study population, sample size, dosage and administration, and further details are outlined in protocol.

### PROGRESS:

23 Sep 96: Nationwide patient accrual has been completed to this protocol. Trial response rates are being determined, but at least 4 partial responses have been documented. No unexpected toxicities were noted. A manuscript is forthcoming. (Dr. Burris/IRB)



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-009 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: A Phase 2 Trial of LY231514 Administered Intravenously Every 21 Days in Patients with Metastatic Colorectal Cancer

START DATE: 11/22/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: CTRC

DEPARTMENT/SERVICE: Med/Hem -Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

Primary objective is to determine the response rate for patients with metastatic colorectal cancer who have been treated with LY231514. Secondary objectives: To characterize the nature of the toxicity of LY231514 in this patient group. To assess pharmacodynamics and population pharmacokinetics of all patients treated with LY231514. To assess the influence of folate status on toxicity of LY231514 by measuring appropriate metabolites. To measure the time to event efficacy variables including survival time, time to progressive disease, time to treatment failure, duration of response for responding patients.

### TECHNICAL APPROACH:

Summary of study design, discussion of design and control, study population and further specifics are outlined in protocol.

### PROGRESS:

Sep 96: Patient accrual to this protocol has been completed nationwide. Promising antitumor activity has been seen, although final response rates have not yet been determined. No unexpected toxicities seen to date.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-012 REPORT DATE: 09/01/96 STATUS: Completed

TITLE: The Measurement of DT-Diaphorase in Normal Volunteers and Colon Cancer Patients

START DATE: 12/04/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Rinaldi, Atkins

DEPARTMENT/SERVICE: Med/Hem -Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The purpose of this pilot study is to determine and compare blood DT-diaphorase gene expression in normal controls, untreated, lightly treated and heavily treated colon cancer patients.

### TECHNICAL APPROACH:

It is proposed that to test the hypothesis that, in patients receiving doxorubicin therapy, radionuclide angiographic and echocardiographic markers of left ventricular diastolic dysfunction reliably precede the loss of left ventricular systolic function. Specifics in protocol.

### PROGRESS:

Sep 96: No patients were accrued to this study at BAMC as all patients were taken from the CTTC and VAH. This study is now officially closed to accrual.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-019 REPORT DATE: 01/05/96 STATUS: Ongoing

TITLE: A Phase I Study of Capecitabine (Ro 09-1978) when Combined with Paclitaxel (Taxol) in Patients with Advanced Solid Tumors

START DATE: 12/15/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: CTRC

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

Primary: To determine the maximum tolerated dose of continuous twice daily oral capecitabine when combined with intravenous paclitaxel administered in 3-week cycles to patients with advanced solid tumors unresponsive to or untreatable by standard therapy. Secondary: To determine the safety profile of the combination regimen of capecitabine and paclitaxel. To study the pharmacokinetic interaction between capecitabine and paclitaxel in patients with advanced solid tumors. To study in an exploratory way the relationship between toxicity and exposure of the body concurrently to (1) capecitabine and its metabolites and (2) paclitaxel. To describe any evidence of antitumor activity of the combination regimen of capecitabine and paclitaxel.

### TECHNICAL APPROACH:

Experimental design and methods, schedule of assessments, patient selection criteria and other specifics are outlined in protocol.

### PROGRESS:

Apr 96: Accrual has proceeded as scheduled. More neutropenia than expected has been observed at early dose levels. Hints of activity in patients with colon cancer have been observed. A minimally tolerated dose should be reached shortly.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-020

REPORT DATE: 09/01/96

STATUS: Ongoing

TITLE: A Phase II Study of Temozolomide (SCH52365) Prior to Radiation Therapy in the Treatment of Patients with Brain Metastases from Malignant Melanoma

START DATE: 12/15/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Rinaldi, Atkins

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

a. To determine the efficacy of SCH 52365 defined as response rate of brain metastases and safety of SCH 52365 when administered orally, once a day for five days repeated every 28 days in the treatment of patients who have brain metastases from malignant melanoma not requiring immediate radiation therapy, previously untreated for this presentation of brain metastases (except for steroids), and who have not received prior chemotherapy for the treatment of malignant melanoma. b. To determine the efficacy of SCH 52365 defined as response rate (complete and partial) of brain metastases and safety of SCH 52365 when administered orally, once a day, for 5 days repeated every 28 days in the treatment of patients who have metastases from malignant melanoma not requiring immediate radiation therapy, previously untreated for this presentation of brain metastases (except for steroids), and who have received previous chemotherapy for the treatment of malignant melanoma.

### TECHNICAL APPROACH:

This is a multinational, multicenter, open label, Phase II study designed to determine the efficacy and safety of SCH 52365 in the treatment of patients who have brain metastases from malignant melanoma not requiring immediate radiation therapy, previously untreated for this presentation of brain metastases, except for steroids, and who may or may not have received previous chemotherapy for the treatment of malignant melanoma.

### PROGRESS:

Aug 96: The single patient enrolled responded nicely to the therapy with a reduction in her lesions. This protocol calls for a very unique patient population, thus the multi-institutional nature of the protocol and expected slow accrual.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-024 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: A Phase I Clinical and Pharmacokinetic Evaluation of LY309887 Administered Every 21 Days in Patients with Metastatic Cancer

START DATE: 12/15/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Aylesworth, Cheryl

ASSOCIATE INVESTIGATOR: CTRC

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

To determine the maximum tolerated dose of LY309887 as a single dose given intravenously once every 21 days with folic acid supplementation given orally for 2 days prior, on the day of, and for 2 days after study drug administration. Secondary objectives are given in protocol.

### TECHNICAL APPROACH:

Investigational Plan and detailed specifics are outlined in protocol.

### PROGRESS:

Sep 96: Accrual has proceeded quickly to this study nationwide. Dose escalation has been limited by myelosuppression. A maximally tolerated dose has most likely been reached and will be confirmed shortly.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-025      REPORT DATE: 09/01/96      STATUS: Ongoing

**TITLE: A Phase I Study of the Safety of Four, Weekly 24-Hour Infusions of Escalating Doses of SU101 in Patients with Solid Tumors**

START DATE: 12/15/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: UTHSCSA/CTRC

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Primary: To assess the maximum tolerated dose of SU101, when given as a series of four weekly, 24-hour infusions in patients with solid tumors. Secondary: To assess the pharmacokinetic/pharmacodynamic profile of multiple doses of SU101, given as a 24-hr infusion, administered once per week for four weeks in patients with solid tumors.

### TECHNICAL APPROACH:

Study design, patient selection, study materials, methods and specific details are outlined in protocol.

### PROGRESS:

Sep 96: Accrual to this protocol has been slow due to the difficult nature of the treatment schedule. No toxicity noted; minimal antitumor activity; dose escalation continues.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-027 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: Phase II/III Trial of 3-Hour Infusions of Paclitaxel from NaPro/Baker Norton in Patients with Refractory Breast Cancer, and a Preliminary Assessment of 96-Hour Infusions

START DATE: 12/18/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Rinaldi, Atkins

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Primary: To confirm the established therapeutic effects of paclitaxel in refractory metastatic breast cancer patients given the approved dose and schedule of a new source of this novel chemotherapeutic agent. Secondary: To confirm the safety profile and patient tolerance characteristics of paclitaxel under the widely accepted therapeutic regimen. To offer a new regimen of paclitaxel (by 96-hr infusion) as a rescue therapy for patients progressing on the standard paclitaxel regimen. To confirm 91. To determine the correlation of mononuclear blood cell (MBC) Mg concentrations with myocardial Mg concentration

### TECHNICAL APPROACH:

Study design, clinical supplies, patient selection and specifics are outlined in protocol.

### PROGRESS:

Sep 96: This trial remains on hold as the sponsor has decided to not yet initiate this trial.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-030 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: A Phase II/III Trial of 3-Hr Infusions of Paclitaxel from NaPro/Baker Norton in Patients with Refractory Ovarian Cancer with Crossover to a 96-Hr Infusion on Failure

START DATE: 12/18/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Rinaldi, Atkins

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine response rate and median time to tumor progression for a 3-hr infusion of paclitaxel from NaPro/Baker Norton in women with ovarian cancer refractory to platinum-based chemotherapy.

### TECHNICAL APPROACH:

Study design, patient selection, treatment plan and specifics are outlined in protocol.

### PROGRESS:

Sep 96: This trial remains on hold as the sponsor has decided to not yet initiate the trial.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-050      REPORT DATE: 02/23/96      STATUS: Ongoing  
TITLE: A Phase II, Open-Label Study of Liarozole in Patients with Advanced Squamous Cell Carcinoma of the Cervix

START DATE: 02/07/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the response rate to liarozole in patients with advanced squamous cell carcinoma of the cervix. Secondary objectives: 1. To determine the time to response in patients with advanced SCC of the cervix responding to liarozole. 2. To determine the time to progression in patients with advanced SCC of the cervix treated with liarozole. 3. To determine the effect of liarozole on the quality of life in patients with advanced SCC of the cervix.

### TECHNICAL APPROACH:

Study design/duration, drugs/dosages, patient inclusion/exclusion criteria and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-051 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: A Phase I Trial of a Fixed Dose of PN401 as a Rescue Agent for Escalating Doses of 5-Fluorouracil (5FU) in the Treatment of Patients with Cancer Refractory to Standard Therapy: Weekly x 3 Schedule

START DATE: 02/08/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/UTHSCSA/

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess the safety and maximum tolerated dose of 5FU when used with a fixed dose of oral PN401, administered on an every 4 week schedule (weekly x 3 followed by one week of rest). To observe for preliminary evidence of antitumor activity.

### TECHNICAL APPROACH:

Patient eligibility, treatment plan, and specifics are outlined in protocol.

### PROGRESS:

Sep 96: Accrual has proceeded slowly - toxicity of predominantly GI fashion has caused changes in dose escalation. Anticipate amendment/modification to be made which would allow the combination of 5FU and PN401 to be given in a tolerable fashion. No abstracts or problems to date.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-052      REPORT DATE: 07/01/96      STATUS: Ongoing

TITLE: A Phase I Study of Temozolomide (SCH 52365) in Combination with Cisplatin in Patients with Advanced Cancer

START DATE: 02/29/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A III

ASSOCIATE INVESTIGATOR: UTHSCSA, CTRC

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

To evaluate the safety profile of SCH 52365 given orally once a day over 5 consecutive days in combination with a single dose of cisplatin administered as a 1-hr intravenous infusion to adult patients with advanced cancer and to determine if the MTD of this combination is lower than the MTD dose of SCH 52365 and the standard dose of cisplatin when these drugs are given individually.

### TECHNICAL APPROACH:

Study design, patient population, conduct of study and further specifics are outlined in protocol.

### PROGRESS:

Jul 96: Patient accrual has proceeded slowly due to the strict eligibility criteria. No unexpected adverse events have been reported to date. No publications or abstracts have been written. Accrual continues per protocol.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-074 REPORT DATE: 06/01/96 STATUS: Ongoing

TITLE: Single Rising Dose Every 3 Weeks, Open Label Study to Demonstrate the Safety, Tolerability, Pharmacokinetics and Preliminary Activity of MDL 101,731 in Patients with Refractory Malignant Solid Tumors

START DATE: 03/01/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A., III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

The objectives of this trial are to determine the following when single doses of MDL 101,731 are administered intravenously every 3 weeks to patients with refractory solid malignancies: 1. To assess the safety and tolerability of single intravenous doses of MDL 101,731 over multiple cycles. 2. To identify the maximum tolerated dose (MTD) and the dose limiting toxicities (DLT) of MDL 101,731. 3. To determine the qualitative and quantitative toxicities of MDL 101,731. 4. To describe any qualitative and quantitative antitumor activity from MDL 101,731. 5. To characterize the preliminary pharmacokinetic profile of MDL 101,731 as determined by measurement of parent drug concentrations in serial plasma samples obtained throughout the dosing period.

### TECHNICAL APPROACH:

Experimental design/methods, subject population, recruitment and further specifics are outlined in protocol.

### PROGRESS:

Jun 96: Only 1 patient has been enrolled. No adverse effects encountered. Accrual has proceeded slowly to this trial. No unusual toxicities to date. No antitumor activity observed. Dose escalation continues.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-075

REPORT DATE: 05/28/96

STATUS: Ongoing

TITLE: A Phase I Multiple-Dose, Dose-Escalation Trial of MDL 101,731 Given as a Weekly Intravenous Infusion

START DATE: 03/06/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A., III

ASSOCIATE INVESTIGATOR: O'Rourke, T; Jenkins, T; Rinaldi, D; Atkins, M

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The following objectives pertain to MDL 101,731 given intravenously once a week for 3 weeks followed by a 1-week rest period: 1. Determine the maximum tolerated dose level. 2. Characterize the dose-limiting toxicity. 3. Characterize plasma and urine pharmacokinetics/pharmacodynamics. 4. Document evidence of antitumor activity when feasible.

### TECHNICAL APPROACH:

The outline for patient population, concomitant medications, study drug, and other specifics are included in protocol.

### PROGRESS:

No report available as of this date. Annual review due Nov 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-078 REPORT DATE: 06/06/96 STATUS: Completed

TITLE: **Irinotecan (CPT-11): Phase II, Open-Label, Prospective Evaluation of Age as a Risk Factor for Development of Toxicities in Patients with 5-Fluorouracil Refractory Colorectal Cancer**

START DATE: 06/03/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Burris, Howard A., III**

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Rinaldi, Atkins

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To determine if age is a risk factor for development of irinotecan-induced diarrhea (the primary endpoint for this study). 2. To determine if age is a risk factor for development of other irinotecan-induced toxicities (a secondary endpoint). 3. To determine the pharmacokinetic profile for irinotecan for patients who are >65 years of age versus those <65 yrs of age. 4. To collect info on the antitumor activity of irinotecan. 5. To collect info on clinical benefit for patients receiving irinotecan.

### TECHNICAL APPROACH:

Eligibility criteria and specifics are outlined in protocol.

### PROGRESS:

Jun 96: Study closed to accrual. Results are being analyzed and manuscript forthcoming (Dr. Burris).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-079      REPORT DATE: 06/11/96      STATUS: Ongoing

TITLE: A Pilot Study to Determine the Usefulness of Phosphatidic Acid and Serum Acyl Chain Ratios for  
Assessing Response to Chemotherapy

START DATE: 06/06/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A., III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC /UTHSCSA/CTRC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine phosphatidic acid levels in serum before and after treatment of cancer patients with chemotherapy and the optimal time for blood collections for best correlation between drug exposure. To determine how this blood test compares with other currently used methods of determining chemotherapy response.

### TECHNICAL APPROACH:

Eligibility criteria, study design, and specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-82ot REPORT DATE: 09/30/96 STATUS: Completed

TITLE: Phase I-II Evaluation of DTIC in the Treatment of Malignant Primary Brain Tumor on a Single Dose Schedule (One-Time)

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/UTHSCSA/CTRC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To determine the maximum tolerated dose of DTIC given as single doses every 28 days with vigorous anti-emetic therapy. 2. To determine the qualitative and quantitative toxicities of DTIC given as a single dose every 28 days. 3. To collect further information about response rates of malignant brain tumor.

### TECHNICAL APPROACH:

Specific drug information, patient eligibility, treatment plan and specifics are outlined in protocol.

### PROGRESS:

Final Note: Patient received cycle 1 of this high dose DTIC at Saint Lukes Baptist Hospital without any side effects. (IRB approval at BAMC) The patient received the second cycle of (one-time) at BAMC. Patient progressed after cycle 2. Patient suffered no significant drug related toxicities.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-086 REPORT DATE: 08/01/96 STATUS: Completed

TITLE: A Phase I Study to Determine the Safety, Tolerance, Pharmacokinetics, and Pharmacodynamics of  
Recombinant Human Thrombopoietin (rhTPO) in Patients with Malignant Neoplasm Receiving  
Thiotepa

START DATE: 09/01/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 5

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 5

### OBJECTIVES:

This Phase I, dose-escalation trial will be a first assessment of the safety, tolerance, pharmacokinetic parameters, and efficacy of rhTPO in a human population.

### TECHNICAL APPROACH:

Eligible patients will be assigned to one of four dose levels of rhTPO, beginning with the lowest dose level. Specifics are outlined in protocol.

### PROGRESS:

Aug 96: Accrual is complete and a manuscript is in preparation. The treatment was well-tolerated and the desired effect was seen. Additional studies are being planned. This report should be considered final.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-087 REPORT DATE: 08/01/96 STATUS: Ongoing

TITLE: A Randomized, Dbl-blind, Placebo Controlled Study to Eval the Effect of Cisplatin/epinephrine  
Injectable Gel (Product MPI 5010) when Admin Intra-tumorally for Achievement of Treatment Goals in  
Recurrent or Refractory Squamous Cell Ca of Head & Neck

START DATE: 04/01/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess achievement of identified treatment goals in patients with recurrent or refractory squamous cell carcinoma of the head and neck following up to 6 weekly intratumoral treatments of cisplatin/epinephrine gel (MPI 5010) compared to placebo gel. To compare the effect of MPI 5010 to placebo gel on local tumor volume and improvement of stabilization in quality of life as measured by FACT-H&N. To compare the time to response and the time to progression after local treatment with MPI 5010 as compared to placebo gel. To compare the histopathology of injected lesions that respond to local treatment as outlined above (biopsy optional).

### TECHNICAL APPROACH:

This will be a multi-center, randomized, double-blind , placebo controlled study in approx 90 evaluable patients with measurable and histologically confirmed recurrent or refractory squamous cell carcinoma of the head and neck.

### PROGRESS:

Aug 96: This protocol was on hold for a prolonged period of time while amendments to the protocol and consent form were being made. Patients had developed "allergic" and adverse reactions to hat was believed to be the epinephrine and the injection technique. The protocol is now in place to resume accrual.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-088

REPORT DATE: 07/15/96

STATUS: Ongoing

TITLE: A Phase I Study to Determine the Safety, Tolerance, Pharmacokinetics, and Pharmacodynamics of Recombinant Human Trombopoietin (rhTPO) in Patients with Malignant Neoplasm Receiving Thiotepa

START DATE: 01/22/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

To determine the safety and tolerance of IV-administered rhTPO in patients with malignant neoplasm receiving thiotepa. To characterize the pharmacokinetic profile of SC-administered rhTPO in patients with malignant neoplasm receiving thiotepa.

TECHNICAL APPROACH:

All patients will receive a single IV injection of rhTPO (Cycle 0, day 0) followed by a 21-day observation period. Figure 1 in study reflects study schema.

PROGRESS:

No report available as of this date. Annual review due Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-124 REPORT DATE: 10/01/96 STATUS: Ongoing

TITLE: Phase I Study of Dexrazoxane Given in Combination with Doxorubicin with Paclitaxel in Patients with Advanced Refractory Solid Tumors

START DATE: 07/15/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC/UTHSCSA/

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To evaluate the maximum tolerable dose (in terms of acute toxicity) of doxorubicin and paclitaxel that can be given to patients that are given concurrent therapy with dexrazoxane. 2. To evaluate the ability of dexrazoxane to act as a cardioprotective agent in those patients receiving combined therapy with doxorubicin and paclitaxel, who receive multiple courses of doxorubicin and paclitaxel (and thus high cumulative doses of doxorubicin). 3. To assess if the addition of escalating paclitaxel doses modifies the systemic exposure (levels) of doxorubicin and dexrazoxane combination chemotherapy in a dose-dependent manner. 4. To assess, relative to historic controls, if the doxorubicin and/or dexrazoxane combination modifies systemic levels of paclitaxel.

### TECHNICAL APPROACH:

Study design, patient eligibility, study drugs, treatment plan and detailed specifics are outlined in protocol.

### PROGRESS:

Due annual review Jun 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-127 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: A Phase I Evaluation of Intravenous MGI 114 Given Daily for Five Days Every Twenty-eight Days in Patients with Advanced Cancer

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris III, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The primary objective of this study is to determine the maximum tolerated dose of HMAF administered intravenously once daily for five days every 28 days in patients with advanced cancer. Secondary: Determine the qualitative and quantitative toxicities of HMAF administered intravenously once daily for five days every 28 days; determine the recommended dose for HMAF to be used in the initial therapeutic trials; determine the basic pharmacokinetics of HMAF by study of plasma and urinary concentrations of the agent in humans; and to collect information about the antitumor effects of HMAF.

### TECHNICAL APPROACH:

Study population, dosage and administration, and specifics are outlined in protocol.

### PROGRESS:

Sep 96: Accrual to this study is proceeding slowly. No unexpected toxicities to date; no responses noted. Dose escalation continues.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-129 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: Irinotecan (CPT-11) - Phase I Study in Refractory Solid Tumor Patients with Hepatic Dysfunction

START DATE: 10/16/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris III, Howard A

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To determine the maximum tolerated dose of irinotecan when administered to patients with hepatic dysfunction. 2. To ascertain the pharmacokinetics/pharmacodynamics of irinotecan and its active metabolites in patients with refractory solid tumors and hepatic dysfunction. 3. To evaluate the qualitative and quantitative toxicities of irinotecan in this patient population. 4. To assess the antitumor activity of irinotecan in this patient population.

### TECHNICAL APPROACH:

Study population, design, dosage, duration of treatment and specifics are outlined in protocol.

### PROGRESS:

Sep 96: Slow accrual at all sites; no unusual toxicities.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-130      REPORT DATE: 07/01/96      STATUS: Ongoing  
TITLE: A Phase I Study of BMS-182248-01 (BR96-Doxorubicin Conjugate) Administered Five Times a Week in  
Patients with Advanced Carcinoma

START DATE: 06/17/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC/CTRC/UTHSCSA

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To evaluate the safety of BMS-182248-01 (BR96-Doxorubicin Conjugate) when given as a one-hr infusion daily for 5 days followed by a two-day rest period for a minimum of eight weeks; to establish the maximum tolerated dose and the recommended phase II dose of BMS-182248-01 administered daily for 5 days followed by a two-day rest period for eight weeks; to describe the pharmacokinetics of BMS-182248-01, total BR96 antibody, total and free doxorubicin, and doxorubicinol after daily infusions of BMS-182248-01.

### TECHNICAL APPROACH:

Patient criteria, concomitant therapy, enrollment, dosing, treatment plan and specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Apr 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-131 REPORT DATE: 09/01/96 STATUS: Ongoing

**TITLE: An Open-Label, Phase 1/2 Ascending Dose Trial of SDZ MKT 077 to Evaluate the Safety, Tolerability and Pharmacokinetic Profile of Single Weekly Doses Administered by IV Infusion Over 30 Minutes in Patients with Refractory Solid Tumors**

START DATE: 12/18/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris III, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the weekly maximum tolerated dose of SDZ MKT 077 when administered by intravenous infusion over 30 minutes in patients with refractory solid tumors. To evaluate the safety, tolerability and pharmacokinetic profile in ascending doses by cohort of SDZ MKT 077 given weekly by IV infusion over 30 minutes in patients with refractory solid tumors.

### TECHNICAL APPROACH:

Investigational plan including all specifics and statistical methods are outlined in protocol.

### PROGRESS:

Sep 96: Slow accrual with other studies having a higher priority.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-132a      REPORT DATE: 09/26/97      STATUS: Ongoing

TITLE: High-Dose Chemotherapy: A Double Bone Marrow Transplant Study for Patients with Metastatic Breast Cancer

START DATE: 09/13/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Brian C.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the toxicity, time to marrow reconstitution, response and time to treatment failure of high-dose combination chemotherapy with taxol, cyclophosphamide and cisplatin, followed by autologous stem cell infusion in eligible patients with metastatic breast cancer.

### TECHNICAL APPROACH:

Patient eligibility, drug information and detailed specifics are outlined in study.

### PROGRESS:

Due annual review Jun 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-132b REPORT DATE: 09/26/97 STATUS: Ongoing

TITLE: High-Dose Etoposide, Cyclophosphamide and Carboplatin (VP-16, CPA, CBDCA) with Autologous Stem cell Rescue (ASCR) and Autologous Granulocyte Infusions for Metastatic Breast Cancer - Part II

START DATE: 09/13/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Brian C.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Propose to study the effects of double high-dose chemotherapy and stem cell rescue in patients with metastatic solid tumors that fail conventional therapy. Plan to study 30 patients under age 65 with metastatic breast tumors and hope to show that this method is both well tolerated and effective in prolonging the disease-free survival in these patients.

### TECHNICAL APPROACH:

Detailed specifics are outlined in protocol.

### PROGRESS:

Annual review due June 1997.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-132c REPORT DATE: 09/26/97 STATUS: Ongoing

TITLE: Autologous Granulocyte Infusions as Supportive Therapy in Breast Cancer Patients Receiving High Dose Chemotherapy with Stem Cell Support

START DATE: 09/13/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Brian C.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

A further study of Granulocyte Storage in a Semi-solid Medium. Rsch Question:  
Can we better characterize and improve the granulocyte storage?

### TECHNICAL APPROACH:

Details are outlined in protocol.

### PROGRESS:

Annual review due June 1997.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-133 REPORT DATE: 08/20/96 STATUS: Ongoing

TITLE: Phase I Clinical and Pharmacokinetic Study to Determine the Safety of Ecteinascidin-743 (ET-743)  
Administered as a Daily Times Five Intravenous Infusion Every 21 Days in Patients with Solid Tumors

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris III, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/UTHSCSA

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the maximum tolerated dose of ET-743 when administered as an intravenous dose daily times five every 21 days. To propose a safe dose for phase II evaluation. To determine the qualitative and quantitative toxic effects of ET-743 and to study the predictability duration, intensity, onset, reversibility and dose-relationship of the toxic side effects.

### TECHNICAL APPROACH:

Eligibility of patients, drug information, trial design and details are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Feb 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-134 REPORT DATE: 08/28/96 STATUS: Ongoing

TITLE: Phase I Study to Determine the Safety of LU 779553 as a 30 Minute Intravenous Infusion Every Day x5,  
Given Every 3 Weeks to Patients with Malignant Solid Tumors

START DATE: 02/26/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris III, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the maximum tolerated dose of LU 79553 when administered as a single 30 minute IV infusion, every day x 5, given every 3 weeks in adult patients with solid tumors. To determine the qualitative and quantitative toxic effects of LU 79553 and to study the predictability, duration, intensity, onset, reversibility and dose-relationship of the toxic side effects. To propose a safe dose (ie near MTD) for phase II evaluation. To study the pharmacokinetics and pharmacodynamics of LU 79553 in man at the different dose levels.

### TECHNICAL APPROACH:

Study population, treatment plan and methods, and further specifics are outlined in protocol.

### PROGRESS:

Annual review due Dec 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-139 REPORT DATE: 07/01/96 STATUS: Completed

TITLE: Irinotecan Hydrochloride (CPT-11): Phase II Trial Using an Every-Other-Week Dosing Schedule in Patients Previously Treated with 5-FU for Colorectal Cancer

START DATE: 06/17/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To determine the antitumor activity of CPT-11 when administered every other week to patients with metastatic colon cancer that has progressed despite prior 5-FU-based chemotherapy. 2. To evaluate the toxicities of CPT-11 on an every-other-week schedule in this patient population. 3. To examine possible relationships between plasma concentrations of CPT-11, SN-38 and SN-38 glucuronide and major toxicities and response. 4. To collect information on clinical benefit for patients receiving CPT-11. 5. To collect information about the incidence and severity of early cholinergic syndrome after CPT-11 administration.

### TECHNICAL APPROACH:

Drug info, patient eligibility, treatment plan and specifics are outlined in protocol.

### PROGRESS:

23 Sep 96: Dr. Burris informed IRB of study closure. (Enrollments were completed at other sites.)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-145 REPORT DATE: 10/03/96 STATUS: Ongoing

TITLE: A Phase I Study of Docetaxel (RP 56976) and Doxorubicin Combination Chemotherapy in Patients with Advanced Solid Tumors

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the maximum tolerated doses (MTD) of docetaxel and doxorubicin in combination, when given to patients with advanced solid tumors. 1. To propose a safe dose level (i.e., maximum acceptable dose {MAD} and schedule for Phase II evaluation in patients with breast cancer and other malignancies. 2. to determine a second MAD for patients receiving cytokine support with G-CSF, if the dose-limiting toxicity in determining the first MAD without cytokine support is neutropenia and/or its complications. 3. To characterize the toxicity of the combination of docetaxel and doxorubicin in patients with advanced solid tumors. 4. To determine the pharmacokinetic profile of docetaxel and doxorubicin when administered in combination.

### TECHNICAL APPROACH:

Entry criteria, plan of study and specifics are outlined in protocol.

### PROGRESS:

Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: REPORT DATE: 06/07/96 STATUS: Ongoing

TITLE: Phase I Study of Taxotere (Docetaxel, RP 56976) for Cancer Patients with Liver Dysfunction Due to Malignancies

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A., III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/UTHSCSA/

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To further investigate the role of tumor-related liver impairment in the toxicity profile of docetaxel in cancerpatients. 2. To define the maximum tolerated dose of docetaxel that can be administered to patients with varying degrees of tumor-related hepatic dysfunction. 3. To determine the pharmacokinetics of docetaxel in patients with various degrees of related hepatic dysfunction.

### TECHNICAL APPROACH:

Patient definition, plan of the study and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Dec 96.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 07/15/96 STATUS: Ongoing

TITLE: Phase 1 Study of Dexrazoxane Given in Combination with Doxorubicin and Paclitaxel in Patients with Advanced Refractory Solid Tumors

START DATE: 07/15/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris III, Howard A.

ASSOCIATE INVESTIGATOR: Oncology staff and fellows

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC/UTHSCSA/

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To evaluate the maximum tolerable dose (in terms of acute toxicity) of doxorubicin and paclitaxel that can be given to patients that are given concurrent therapy with dexrazoxane. 2. To evaluate the ability of dexrazoxane to act as a cardioprotective agent in those patients receiving combined therapy with doxorubicin and paclitaxel, who receive multiple courses of doxorubicin and paclitaxel. Etc.

### TECHNICAL APPROACH:

Study design, population, eligibility criteria and further details are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due May 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 08/06/96 STATUS: Ongoing

TITLE: Phase I Trial of Rhizoxin (NSC 332598) Administered as a 72 Hour Continuous Intravenous Infusion Every 21 Days

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Aylesworth, Cheryl A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To determine the maximum tolerated dose (e.g., that dose associated with clinically acceptable, predictable and reversible toxicity) of rhizoxin given on a 72-hr continuous infusion schedule. 2. To determine the qualitative and quantitative toxicities of rhizoxin given on a 72-hr continuous infusion schedule. 3. To determine the recommended dose for rhizoxin on a 72-hr continuous infusion schedule to be used in phase II trials. 4. To characterize the pharmacokinetics/pharmacodynamics of rhizoxin. 5. To collect information about antitumor effects of rhizoxin.

### TECHNICAL APPROACH:

Drug information, eligibility criteria, treatment plan and specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 08/20/96 STATUS: Ongoing

TITLE: Irinotecan Hydrochloride (CPT-11): Phase II Trial Using an Every-Other-Week Dosing Schedule in Patients Previously Treated with 5-FU for Colorectal Cancer (M6475/0033)

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris III, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the antitumor activity of CPT-11 when administered every other week to patients with metastatic colon cancer that has progressed despite prior 5-FU-based chemotherapy. To evaluate the toxicities of CPT-11 on an every-other-week schedule in this patient population. To examine possible relationships between plasma concentrations of CPT-11, SN-38 and SN-38 glucuronide and major toxicities and response. To collect information on clinical benefit for patients receiving CPT-11. To collect information about the incidence and severity of early cholinergic syndrome after CPT-11 administration.

### TECHNICAL APPROACH:

Drug information, eligibility criteria, treatment plan and specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due May 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending

REPORT DATE: 08/27/96

STATUS: Ongoing

TITLE: Phase I Evaluation of CGP 64128A (ISIS 3521) Administered as a Two Hour Intravenous Infusion Three Times per Week, for Three Consecutive Weeks, in patients with Cancer

START DATE: 01/22/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris III, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

Primary objective of this study is to determine the maximum tolerated dose of CGP 64128A when administered as a two hour IV infusion, three times per week, for three consecutive weeks. The maximally tolerated dose is defined as the dose level immediately below the dose level which produced dose-limiting toxicity.

TECHNICAL APPROACH:

Study design, patient population, clinical supplies, study procedure and specifics are outlined in protocol.

PROGRESS:

No report available as of this date. Annual review due Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 08/28/96 STATUS: Ongoing

TITLE: A Phase I Trial of Gemcitabine Plus Vinorelbine Combination Therapy in patients with Refractory Solid Tumors

START DATE: 02/26/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rinaldi, David A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC1/CTRC/UT

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Primary objective is to determine the MTD and DLT of gemcitabine plus vinorelbine combination therapy when administered on Days 1, 8, and 15 every 28 days to patients with refractory solid tumors.

### TECHNICAL APPROACH:

Study design, population, dosage/administration and specifics are outlined in protocol.

### PROGRESS:

To be reviewed Dec 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 08/28/96 STATUS: Ongoing

TITLE: Phase I Trial of Rhizoxin (NSC 332598) Administered as a 72-Hr Continuous Intravenous Infusion Every 21 Days

START DATE: 08/15/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rinaldi, David A.

ASSOCIATE INVESTIGATOR: O'Rourke, Jenkins, Cobb, Burris, Atkins

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the maximum tolerated dose (e.g., that dose associated with clinically acceptable, predictable and reversible toxicity) of rhizoxin given on a 72 hour continuous infusion schedule. To determine the qualitative and quantitative toxicities of rhizoxin given on a 72 hr continuous infusion schedule. To determine the recommended dose for rhizoxin on a 72 hr continuous infusion schedule to be used in phase II trials. To characterize the pharmacokinetics/pharmacodynamics of rhizoxin. To collect information about antitumor effects of rhizoxin.

### TECHNICAL APPROACH:

Drug information, eligibility criteria, treatment plan, and specifics are outlined in protocol.

### PROGRESS:

To be reviewed Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 09/01/96 STATUS: Ongoing  
TITLE: A Phase I Protocol to Determine Safety, Tolerability, Pharmacokinetics and Maximum Tolerated Dose  
of CGP 48664 in Cancer Patients

START DATE: 10/16/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rinaldi, David A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To establish safety and tolerability of CGP 48664 in cancer patients. To establish a maximum tolerated dose of CGP 48664 in cancer patients after one cycle of treatment. To obtain pharmacokinetic data on CGP 48664 in cancer patients.

### TECHNICAL APPROACH:

Investigational plan including design, dose escalation schedule , toxicity, sample size and specifics are outlined in protocol.

### PROGRESS:

Sep 96: No patients have been enrolled to date as the protocol has not been officially opened with regard to drug delivery or site initiation.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: Phase I Study to Determine the Safety of LU 103793 as a 5-Min. I.V. Infusion, Every Other Day x 3,  
Given Every 3 Weeks to Patients with Malignant Solid Tumors

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rinaldi, David A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Determine the maximum tolerated dose of LU 103793 when administered as a single 5-min I.V. infusion, every other day x 3, given every 3 weeks in adult patients with solid tumors; to determine the qualitative and quantitative toxic effect of LU 103793 and to study the predictability, duration, intensity, onset and reversibility of the toxic side effects; to propose a safe dose (i.e. near MTD) for phase II evaluation; to study the pharmacokinetics of LU 103793 in man at the different dose levels, and to evaluate the rationale for this schedule; to document any possible antitumor activity.

### TECHNICAL APPROACH:

Trial design, study population, treatment plan and methods, and specifics are outlined in protocol.

### PROGRESS:

Sep 96: Accrual has recently been initiated to this schedule. Other schedules have been limited by myelosuppression and liver toxicity. No activity or toxicity noted to date on this schedule.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 10/01/96 STATUS: Ongoing

TITLE: A Phase I Dose Finding Clinical Trial to Evaluate the Safety and Pharmacokinetics of DMP 840 in Combination with Cisplatin Given Every Three Weeks (Q3W) in Patients with Advanced Cancer

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rinaldi, David A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the maximum tolerated doses of the combination of cisplatin (administered first as a 1 hr infusion) and DMP 840 (administered second as a 1 hr infusion) on a every 3-wk (q3w) schedule in patients with cancer refractory to conventional therapy or in patients for whom no standard therapy exists. Secondary objectives of this study are to characterize the safety and toxicity profile of DMP 840 when administered in combination with cisplatin, and to define their duration and reversibility.

### TECHNICAL APPROACH:

Study design, duration, study periods and specifics are outlined in protocol.

### PROGRESS:

To be reviewed Oct 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-pend REPORT DATE: 01/18/96 STATUS: Ongoing

TITLE: A Phase I Trial of Bizelesin (NSC 61529) Using a Single Dose (10 minute infusion) Given Every 28 Days  
in Patients with Advanced Cancer

START DATE: / /

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine: 1. the maximum tolerated dose of bizelesin given as a ten minute infusion repeated every 28 days. 2. the qualitative and quantitative toxicities of bizelesin given as a ten minute infusion repeated every 28 days. 3. To characterize the pharmacokinetics of bizelesin administered as a ten minute infusion. 4. To determine the recommended dose of bizelesin given as a ten minute infusion repeated every 28 days to be used in Phase II trials. 5. To collect information about the antitumor effects of bizelesin in patients with advanced cancer.

### TECHNICAL APPROACH:

Drug information, eligibility criteria, treatment plan, pharmacokinetics and further specifics are outlined in protocol.

### PROGRESS:

Jan 96: Due to drug availability issues centering around toxicology, accrual has not been initiated. No definite starting date is available at present.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 10/04/96 STATUS: Ongoing

TITLE: A Phase I, Open Label, Ascending Dose Study of Vesnarinone in Combination with Gemcitabine in Patients with Advanced Cancer

START DATE: 08/19/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To determine the maximum tolerated dose of vesnarinone in combination with gemcitabine in patients with advanced cancer.
2. To assess the safety and determination with gemcitabine.
3. To determine the plasma levels of the combination of vesnarinone and gemcitabine in patients with advanced cancer.
4. To assess preliminary efficacy in patients treated with vesnarinone in combination with gemcitabine.

### TECHNICAL APPROACH:

Design, subject population, plan and specifics are outlined in protocol.

### PROGRESS:

Due annual review Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 10/04/96 STATUS: Ongoing

TITLE: Phase I Trial of LY231514 Given with Folic Acid Supplementation in Patient with Locally Advanced or Metastatic Cancer

START DATE: 08/19/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A. III

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the MTD of LY231514 when administered as a 10-minute infusion every 3 weeks given with oral folic acid supplementation for 2 days prior, on the day of, and for 2 days after study drug administration to patients with locally advanced or metastatic cancer.

### TECHNICAL APPROACH:

Plan design, population, dosage administration and specifics are outlined in protocol.

### PROGRESS:

Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 10/07/96 STATUS: Ongoing

TITLE: Compassionate Use Mitoguazone Dihydrochloride in Refractory or Relapsed Non-Hodgkin's Lymphoma--Non-AIDS Related

START DATE: 08/19/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Aylesworth, Cheryl a.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To compassionately treat with Mitoguazone dihydrochloride (MGBG) in patients with refractory or relapsed non-Hodgkin's lymphoma. 2. To define qualitative and quantitative toxicities of Mitoguazone dihydrochloride.

### TECHNICAL APPROACH:

Drug information, staging/histology criteria, treatment plan and specifics are outlined in protocol.

### PROGRESS:

Due Annual Review Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 10/30/96 STATUS: Ongoing

TITLE: Extended Administration of Temozolomide (SCH 52365) in Patients with Advanced Cancer

START DATE: 09/23/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: Atkins, Aylesworth, Bloss, Drengler, Eckhardt, Hall,  
Hammond, etc.

DEPARTMENT/SERVICE: Med/Hem-Onc

FACILITY: BAMC/CTRC/UTH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To continue providing temozolomide to patients with advanced cancers who have responded (stable disease, partial or complete response) to SCH 52365 treatment after completion of 6 cycles on a parent Schering-Plough Phase I protocol. To characterize the safety and antitumor activity of SCH 52365 patients receiving extended administration of SCH 52365.

### TECHNICAL APPROACH:

Study design, population, subject inclusion/exclusion criteria, and further specifics are outlined in protocol.

### PROGRESS:

Annual review due Aug 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: Pending REPORT DATE: 10/30/96 STATUS: Ongoing

TITLE: A Phase I Study of LY231514 and 5-Fluorouracil in Patients with Locally Advanced or Metastatic Cancer

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burris, Howard A.

ASSOCIATE INVESTIGATOR: Atkins, Aylesworth, Bloss, Drengler, Eckhardt, Hall, Hammond, etc.

DEPARTMENT/SERVICE: Med/Hem-Onc FACILITY: BAMC/CTRCL/UT

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Primary objective is to determine the MTD of LY231514 and 5-FU combination therapy administered every 21 days in patients with locally advanced or metastatic cancer. Secondary: To collect information about the antitumor effects of LY231514 and 5-FU in combination; to determine the qualitative and quantitative toxicities of LY231514 and 5-FU on this schedule; to determine the recommended doses for LY231514 and 5-FU on this schedule for subsequent Phase 2 trials; and to determine the pharmacokinetics of LY231514 and 5-FU in combination.

### TECHNICAL APPROACH:

Study design, inclusion/exclusion criteria for enrollment, dosage, administration and further specifics are outlined in protocol.

### PROGRESS:

Annual review due Aug 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-86-060 REPORT DATE: 05/01/96 STATUS: Terminated

TITLE: Natural History of HTLV-III Infection and Disease in a United States Military Population

START DATE: 06/25/86

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Dooley, David

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Infec Dis

FACILITY: BAMC

KEY WORDS: HTLV-III

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 60

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 570

### OBJECTIVES:

1. To assess the impact of HTLV-III infection on fitness for duty (deployability, military readiness and retention) by systematically defining the natural disease progression in individuals with documented HTLV-III infections in the general military population (active duty, dependents and retirees).

### TECHNICAL APPROACH:

Each HTLV-III infected individual will be staged according to the Walter Reed Staging Classification. The only additional requirements of individuals enrolled in this study are (1) additional information gathered from each individual as a consequence of this study will be centralized in a common data base; (2) serum and CSF will be stored at WRAIR for future testing.

### PROGRESS:

May 96: No new enrollments last 12 months. This was left open in anticipation of WRAIR wanting to infuse money and jump-start it (it was "mothballed" at least 3 years ago). They've not done so. Therefore terminate.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-87-052      REPORT DATE: 04/01/96      STATUS: Ongoing

TITLE: Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma, Using Ex-Vivo Marrow Treatment with 4-Hydroperoxycyclophosphamide (4-HC)

START DATE: 05/13/87      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Myhand, Rick C.

ASSOCIATE INVESTIGATOR: Thomas, Paul; Potter, Al; Zaloznik, Arlene; Reeb, Barbara

DEPARTMENT/SERVICE: Med/Hem-Onc      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

1. To evaluate autologous marrow rescue after intensive therapy in patients with acute leukemia and lymphoma in second remission or subsequent remission or in early relapse. 2. To study the effects of ex vivo bone marrow purging utilizing 4-HC on malignant cells, marrow stem cells, and relationship to subsequent engraftment times. 3. To study the acute toxic effects of the preparative regiments.

### TECHNICAL APPROACH:

To be eligible for this study, all patients must have a diagnosis of acute leukemia or aggressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission. Therapy will follow the schema outlined in the study protocol.

### PROGRESS:

Apr 96: One patient enrolled for follow-up. No complications.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-014 REPORT DATE: 01/01/96 STATUS: Completed

TITLE: Active Immunization of Early HIV Infected Patients with Recombinant GP160 HIV Protein: Phase II  
Study of Toxicity Immunotherapy, In Vivo Immunoregulation and Clinical Efficacy

START DATE: 01/08/91 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Davis, Charles

ASSOCIATE INVESTIGATOR: McAllister, Kenneth

DEPARTMENT/SERVICE: Med/Infec Dis

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To conduct a Phase 2 trial of the recombinant human immunodeficiency virus envelope glycoprotein, GP160 candidate vaccine, in patients with early HIV infection (Walter Reed Stage 1-2). Specific objectives include: 1. To continue to evaluate the immunogenicity and toxicity of this produce; 2. To determine the parameters predictive of immuneresponsiveness; and 3. To determine the clinical efficacy of immunization with GP160 in the treatment of early HIV infection.

### TECHNICAL APPROACH:

As outlined in the study protocol.

### PROGRESS:

Jan 96: This study was completed 30 Nov 95. Awaiting analysis of data.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-018      REPORT DATE: 02/15/96      STATUS: Ongoing

TITLE: The Natural History of HIV Infection and Disease in US Military Beneficiaries.

START DATE: 02/01/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Dooley, David R.

ASSOCIATE INVESTIGATOR: Dooley, David

DEPARTMENT/SERVICE: Med/Infec Dis

FACILITY: BAMC/WRAIR

KEY WORDS: HIV

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 131

### OBJECTIVES:

a. To systematically document the natural disease progression in individuals with HIV infections in a general military population. b. To form a study cohort which will be eligible for participation in treatment protocols and for other studies related to specific aspects of the descriptive elements (natural history) of HIV infection.

### TECHNICAL APPROACH:

Proposal is to organize information in a data base now being routinely collected on HIV patients with a data base, henceforth referred to as the BAMC Natural History Study, in such a way that more scientifically valid information will be forthcoming and safeguards to patient confidentiality are met.

### PROGRESS:

Feb 96: This study is on hold. No new patients have been enrolled, none are being followed, and no data is being collected on any previously enrolled patients. If WRAIR does not want to do anything (give \$) to reopen this I anticipate shutting it down next year. (Dr. Dooley)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-053      REPORT DATE: 09/01/96      STATUS: Ongoing  
TITLE: Core Protocol for HIV Developmental Diagnostic (Adults)

START DATE: 05/01/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Dooley, David

ASSOCIATE INVESTIGATOR: Burke, Donald S.

DEPARTMENT/SERVICE: Med/Infec Dis

FACILITY: BAMC/WRAMC

KEY WORDS: HIV

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 90  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 146

### OBJECTIVES:

a. To develop and evaluate new and/or improved laboratory methods for establishing the diagnosis of HIV, and to correlate detectable HIV virus, HIV antigen, and/or HIV nucleic acid in blood with clinical status. b. To develop and evaluate new and/or improved lab methods for assessing the virus specific immune response to HIV infection, and to correlate detection of virus specific antibody or cell mediated immune responses with clinical status.

### TECHNICAL APPROACH:

Under this protocol, the patient will be asked to give informed consent that his/her blood can be used for the general purpose of development and evaluation of virologic and immunologic technologic techniques, and that his/her clinical records can be reviewed in order to correlate test results with his/her clinical condition.

### PROGRESS:

Approximately 146 subjects have been enrolled to date. Serum and cells from these patients have been banked for use in development of diagnostic methods.  
Sep 96: Attempting to obtain funding to possibly continue to accrue patients.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-018

REPORT DATE: 01/01/96

STATUS: Ongoing

TITLE: Monokine Induction in Patients Infected with Coccidioides Immitis

START DATE: 11/16/92

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Dooley, David P.

ASSOCIATE INVESTIGATOR: Cox, Rebecca A.

DEPARTMENT/SERVICE: Med/Infec Dis

FACILITY: SA Chest

KEY WORDS: Monokine; Coccidioides; Immitis

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 52

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 73

### OBJECTIVES:

To determine whether infection with the fungus Coccidioides immitis causes an increased production of the monokines tumor necrosis factor - a (TNF-a), interleukin-1 beta (IL-1B), and interleukin 6 (IL-6) in patients with coccidioidomycosis. Specific aims include the comparison of the in vitro monokine responses of blood monocytes from six study groups.

### TECHNICAL APPROACH:

Description of subjects/controls; criteria for inclusion/exclusion; experimental design/methods; data collection; statistical analysis and specifics outlined in protocol.

### PROGRESS:

Nov 95: One additional patient at BAMC has been enrolled in this study; no complications or adverse reactions have occurred as the result of this study. Across the 3 participating institutions, 52 subjects were enrolled during the reporting period; 73 subjects have been enrolled to date.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-049

REPORT DATE: 12/01/95

STATUS: Ongoing

TITLE: Monokine Production in Patients Co-Infected with Mycobacterium Tuberculosis and the Human Immunodeficiency Virus

START DATE: 12/23/92

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Dooley, David P.

ASSOCIATE INVESTIGATOR: Anders, Greg; Cox, Rebecca A; Kemp, Kenneth

DEPARTMENT/SERVICE: Med/Infec Dis

FACILITY: BAMC/SA Chest

KEY WORDS: Monokine; Mycobacterium Tuberculosis; Immunodeficiency Virus

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

The goal of this investigation is to determine if tuberculosis causes an increased production of the monokines tumor necrosis factor-alpha (TNF-a), interleukin-13 (IL-1), and interleukin-6 (IL-6) in persons infected with the human immunodeficiency virus (HIV). The specific aims will be to compare the in vitro monokine responses of purified blood monocytes, total peripherinuclear cells, and alveolar macrophages from four study groups.

### TECHNICAL APPROACH:

Description of subjects/controls, experimental design/methods, data collection and statistical analysis included in protocol.

### PROGRESS:

Dec 95: No additional BAMC patients have been enrolled in this study; 2 additional State Chest Hospital donors were enrolled by Dr. Kemp before his departure. The study is on hold pending the acquisition of additional funding/bench personnel support.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-088 REPORT DATE: 04/01/96 STATUS: Ongoing

TITLE: A Blinded, Randomized Trial Comparing Zidovudine (ACV) vs ZDV + Didanosine (ddI) vs ZDV + ddI + Nevirapine in Asymptomatic Patients on ADV Monotherapy Who develop a Mutation at Codon 215 of HIV Reverse Transcriptase in Serum/Plasma Viral RNA

START DATE: 04/14/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Dooley, David

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Infec Dis

FACILITY: BAMC

KEY WORDS: Zidovudine (ACV), Didanosine, mutation, transcriptase, serum/plasma,

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 5

### OBJECTIVES:

Primary: 1. To validate that alternation of codon 215 of reverse transcriptase in plasma virus precedes the increase in viral burden as measured in the peripheral blood and decline in CD4 count which have been observed in association with clinical failure on zidovudine. 2. To determine whether alternative regimens of antiretroviral agents alter the course of viral burden as measured in the peripheral blood and CD4 changes when initiated on the basis of plasma LRNA PCR results.

### TECHNICAL APPROACH:

Patient selection/enrollment, study treatment, clinical/laboratory evaluations and other specifics are outlined in protocol.

### PROGRESS:

Apr 96: Total patients followed: 5. Total screened for study: 9 (4 ineligible). Expected duration of study - Dec 96 (possible premature conclusion).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-089      REPORT DATE: 03/01/96      STATUS: Ongoing  
TITLE: A Randomized, Controlled, Multicenter Trial of Filgrastim (Recombinant-Methionyl Human Granulocyte Colony Stimulating Factor) for the Prevention of Grade 4 Neutropenia in Patients with HIV Infection  
START DATE: 04/05/94      ESTIMATED COMPLETION DATE: / /  
PRINCIPAL INVESTIGATOR: McAllister, Kenneth  
ASSOCIATE INVESTIGATOR: Dooley  
DEPARTMENT/SERVICE: Med/Infec Dis      FACILITY: BAMC  
KEY WORDS: Filgrastim, Human Granulocyte colony Stimulating Factor, Grade 4  
NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

To determine the efficacy of Filgrastim (r-metHuG-CSF) for the prevention of Grade 4 neutropenia (ANC<500/mm3) in patients with HIV infection. Secondary: To compare the incidence of culture confirmed bacterial infections and fungal infections, use of IV antibacterial and antifungal agents, use of myelosuppressive drugs, and hospitalizations in patients randomized to Filgrastim treatment versus patients randomized to observation. To compare all adverse events and the incidence of death in patients randomized to Filgrastim treatment versus patients randomized to observation.

### TECHNICAL APPROACH:

Background and rationale, experimental plan, patient eligibility/enrollment, study drugs, treatment procedures and further details are outlined in protocol.

### PROGRESS:

On 11 May 94 first patient (AJS 2401) was enrolled and remained on protocol until 24 Oct 94 without side effects related to GCSF. Since then, patient continued on open-label Filgrastim 300mg three times a week until Apr 95 at which time Dr. Kasper at the Audie Murphy VA Hospital discontinued drug. On 30 May 95, Filgrastim was restarted at 300mg weekly. Patient continues to require GCSF to maintain a white blood cell count of greater than 5,000. Other potential candidates that might have benefited from GCSF did not have an absolute neutrophil count between 500 and 1,000 or could not participate in the study due to logistical problems. As of Aug 95, new patient enrollment was closed. The aforesaid patient continues to do well on GCSF and the open-label program will be needed as long as he is alive.  
Mar 96: This double blinded study is to continue next 4-5 years. The two patients are tolerating fine, no side effects.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-022      REPORT DATE: 02/12/96      STATUS: Terminated

TITLE: A Randomized, Multicenter, Investigator-Blind Trial Comparing Intravenous CP-116,517 Followed by Oral CP-99, 219 w/Intravenous Ciprofloxacin and Ampicillin followed by Oral Ciprofloxacin and Amoxicillin for the Treatment of Community Acquired Pneumonia

START DATE: 02/06/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Dooley, David P.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Infec Dis      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the efficacy of sequential therapy with intravenous CP-116, 517 followed by oral CP-99, 219 as empiric monotherapy compared to intravenous ciprofloxacin and ampicillin followed by oral ciprofloxacin and amoxicillin in the treatment of patients with community acquired pneumonia which requires initial hospitalization and intravenous therapy. to compare the safety and toleration of CP-116, 517 and CP-99, 219 to ciprofloxacin and ampicillin/amoxicillin.

### TECHNICAL APPROACH:

Study population, treatments, patient evaluation visits and further specifics are outlined in protocol.

### PROGRESS:

Company closed BAMC site before anyone was enrolled.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-128 REPORT DATE: 09/18/96 STATUS: Ongoing

TITLE: **DdI Single Dose vs Twice Daily Dosing with and without Hydroxyurea Using the DdI Pediatric Suspension Powder in HIV Positive Individuals**

START DATE: 09/12/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Dooley, David P.

ASSOCIATE INVESTIGATOR: Dyal, Rusnak (WHMC)

DEPARTMENT/SERVICE: Med/Infec Dis

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the efficacy of once daily ddI therapy using the same currently total daily recommended dosage of ddI compared to the currently recommended twice daily regimen in HIV patients, and to also compare each of the above drug regimens in combination with hydroxyurea to ddI therapy alone.

### TECHNICAL APPROACH:

Inclusion/exclusion criteria and further specifics are outlined in protocol.

### PROGRESS:

Annual review due Aug 1997.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-138 REPORT DATE: 09/27/96 STATUS: Ongoing

TITLE: Evaluation of the Effect of Combination Azithromycin and Fluconazole on the QT Interval in Both Healthy and HIV Infected Subjects

START DATE: 09/26/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Coble, Pecos

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Infec Dis FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The goal of this study is to determine the potential risk of prolonged QT interval in HIV infected and healthy subjects while being treated with azithromycin alone and azithromycin and fluconazole in combination.

### TECHNICAL APPROACH:

Azithromycin and fluconazole are common therapies in HIV infected patients for a variety of indications. They are often used in combination. However, there are no data on the potential for either of these drugs to cause prolonged QT interval with the subsequent potential for arrhythmias. Although there are studies on drugs from the same classes of each which indicate this could be a potential problem, there have been no reported symptomatic or fatal arrhythmias attributed to either of these drugs or the combination thereof.

### PROGRESS:

Due annual review Mar 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-147 REPORT DATE: 10/10/96 STATUS: Ongoing

TITLE: **The Effect of Moving to a New Hospital Facility on the Prevalence of Endemic Resistant Nosocomial Pathogens**

START DATE: 03/22/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Dooley, David P.**

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Infec Dis FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The goal of this study is to determine whether the move to the new BAMC hospital building, with the concomitant improved ability to implement adequate infection control practices, will be associated with a reduction in the frequency of resistant endemic nosocomial pathogens.

### TECHNICAL APPROACH:

Eligibility/exclusion criteria, experimental design/methods and specifics are outlined in protocol.

### PROGRESS:

Due Annual Review Feb 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-90-040      REPORT DATE: 02/01/96      STATUS: Ongoing

TITLE: Prostaglandin Excretion of Radiocontrast Induced Acute Renal Failure

START DATE: 03/12/90      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Wortham, William

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Neph      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 5

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 8

### OBJECTIVES:

To determine if prostaglandins are diminished in response to radiocontrast administration in the human subject. Further to determine if the decrement, if noted, correlates with a change in renovascular resistance, renal blood flow and/or creatinine clearance during the acute period surrounding radiocontrast administration.

### TECHNICAL APPROACH:

Participants will be admitted 24 hours prior to cardiac catheterization for collection of a 24-hr urine sample for sodium and prostaglandin metabolites, thromboxane B2 and 24-hr creatinine. In addition, they will undergo a nuclear determination via plasma clearance, I131 Hippuran and DTPA to determine renal blood flow as well as GFR via radionuclide study 4-6 hrs prior to catheterization, they will receive volume status. At cardiac catheterization, a determination of central venous pressure will be necessary. Immediately after contrast administration, a second spot renin and catechol determination will be made. After cardiac catheterization a 24-hr urine will be collected for prostaglandin metabolites and sodium and creatinine as well as routine serum creatinine and electrolytes. An I131 Hippuran and DTPA for determination of renal plasma flow and glomerular filtration will be obtained 24 hrs post cardiac catheterization.

### PROGRESS:

Feb 96: Study ongoing. Now having decreased enrollment secondary to time constraint, other assignments (Officer Adv Crs). No adverse affects encountered.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-068 REPORT DATE: 08/01/96 STATUS: Terminated

TITLE: Prophylactic Low Dose Coumadin and Antiplatelet Therapy in the Nephrotic Syndrome Secondary to Membranous Nephropathy

START DATE: 07/01/92 ESTIMATED COMPLETION DATE: 06/01/97

PRINCIPAL INVESTIGATOR: Seiken, Gail L.

ASSOCIATE INVESTIGATOR: Gouge, Steven F.

DEPARTMENT/SERVICE: Med/Neph

FACILITY: BAMC

KEY WORDS: Prophylactic; Coumadin; Antiplatelet Therapy; Nephrotic Syndrome

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To prospectively examine the incidence of thrombotic events in patients with nephrotic syndrome secondary to membranous nephropathy. 2. To prospectively evaluate the role of low dose coumadin and antiplatelet therapy in the prevention of thrombotic complication of nephrotic syndrome secondary to membranous nephropathy. 3. To prospectively evaluate the benefit of anticoagulation in patients with documented thrombosis associated with the nephrotic syndrome of membranous nephropathy.

### TECHNICAL APPROACH:

This is a prospective, randomized study designed to evaluate the incidence of thromboembolic complications in patients with idiopathic membranous glomerulopathy, and the potential role for prophylactic low dose coumadin and antiplatelet therapy in the prevention of these complications.

### PROGRESS:

Jun 95: No patients entered into the study. All information current. Study remains ongoing for patient accrual.

Aug 96: PI has PCS'd to WRAMC. Dr. Wortham study terminated; no one else interested in pursuing it.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-024 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: Comparison of the Effects of Nifedipine and Isradipine on Urinary Albumin Excretion and Blood Pressure in Patients with Type Two Diabetes, Hypertension and Proteinuria

START DATE: 01/04/92 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Abbott, Kevin C.

ASSOCIATE INVESTIGATOR: Barr, James G; Bakris, George L; Patton, Beverly

DEPARTMENT/SERVICE: Med/Neph

FACILITY: BAMC

KEY WORDS: Nifedipine; Isradipine; Urinary Albumin; Blood Pressure; Diabetes

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 9

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 9

### OBJECTIVES:

This trial will evaluate the effects of isradipine and a sustained release formulation of nifedipine, Procardia XL, on arterial pressure and renal function. Renal function will be determined by twenty-four urine collections for creatinine clearance, fractional excretion of sodium, albumin and protein excretion.

### TECHNICAL APPROACH:

Subjects with type II diabetes with mild to moderate hypertension (defined in protocol) and urinary protein excretion of greater than one gram per twenty-four hours will be enrolled in the study. Age for eligibility will be 45 years or greater.

### PROGRESS:

Jan 96: If a medical resident is unable to participate by March 1996 will consider study completed.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-033 REPORT DATE: 01/29/96 STATUS: Ongoing

TITLE: Non-linear time series analysis of dialytic arterial and venous pressures to forecast vascular access thrombosis

START DATE: 01/02/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Abbott, Kevin C.

ASSOCIATE INVESTIGATOR: Seiken, Wortham

DEPARTMENT/SERVICE: Med/Neph

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Prospective Trial to evaluate the utility of intensive time series analysis of venous and arterial pressures of vascular accesses of patients undergoing maintenance hemodialysis as a means to forecast vascular access thrombosis (VAT).

### TECHNICAL APPROACH:

Sample size calculations, statistical methods, impact on patients and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-90-024      REPORT DATE: 02/01/96      STATUS: Terminated  
TITLE: Induction of TNFa and IL-1 in Human Tuberculosis

START DATE: 02/05/90      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Anders, Gregg T.

ASSOCIATE INVESTIGATOR: Kelly, William; McAllister, Kenneth

DEPARTMENT/SERVICE: Med/Pulm Dis      FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The objective of this study is to determine the extent of tumor necrosis factor-alpha (TNF-a) and interleukin 1 (IL-1) production association with human tuberculosis. Peripheral blood monocytes cells (PBMC) from patients with positive purified protein derivative (ppd) skin reactions or active tuberculosis will be compared with healthy controls (PPD negative) by in vitro stimulation with mycobacterial antigens and killed Mycobacterium tuberculosis and the concurrent production of TNF-a and IL-1 measured by ELISA.

### TECHNICAL APPROACH:

Patients and healthy controls (staff volunteers) will be phlebotomized approximately 50 ml of blood by peripheral venipuncture. In vitro antigen stimulation of PBMC and measurement of TNF-a and IL-1 production by ELISA will be performed.

### PROGRESS:

Feb 96: Patient accrual has been zero due to difficulties in obtaining active cases at BAMC. One associate investigator has left the Army. Termination requested.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-011 REPORT DATE: 02/01/96 STATUS: Ongoing

TITLE: **The Effect of Oxygen Breathing Upon Lung Machines in Patients with Emphysema**

START DATE: 02/03/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Johnson, James**

ASSOCIATE INVESTIGATOR: Kumke, Kevin; Honeycut, Wayne; Blanton, H.M.; Anders, Gregg

DEPARTMENT/SERVICE: Med/Pulm Dis

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 58

### OBJECTIVES:

To study the effects on lung mechanics of breathing 50% oxygen balance nitrogen versus breathing 21% oxygen balance nitrogen in a group of emphysematous patients with moderately severe disease.

### TECHNICAL APPROACH:

Patients undergo forced vital capacity, thoracic gas volume, airway resistance and compliance measurement before and after breathing 21% O<sub>2</sub> and 50% O<sub>2</sub> (double-blinded).

### PROGRESS:

Feb 96: No new patients added but desire study remain open.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-028      REPORT DATE: 02/01/96      STATUS: Terminated

TITLE: Exercise Induced Oxyhemoglobin Desaturation as a Predictor of Nocturnal Desaturation in Chronic Obstructive Pulmonary Disease Patients

START DATE: 02/06/91      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Honeycutt, Wayne T.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Pulm      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 13

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 33

### OBJECTIVES:

To determine whether exercise induced oxyhemoglobin desaturation in moderate to severe chronic obstructive pulmonary disease (COPD) patients can predict those who will have significant nocturnal desaturation.

### TECHNICAL APPROACH:

Approximatel 40-50 subjects will be studied. Each patient will undergo an initial history and phyusical examination. Pulmonary function tests will be performed on the Sensor Medics Horizon System to include pre- and post-bronchodilator forced vital capacity (FVC) and FEV1. Lung volumes and diffusion capacity for carbon monoxide will be measured. Resting arterial blood will be obtained in the supine position on room air. Desaturation with exercise will be evaluated during cardio-pulmonary testing using the Minolta Pulse-Oximeter. Nocturnal respiratory excursions, nasal airflow, ECG and oxyhemoglobin saturation will be monitored with an ambulatory system.

### PROGRESS:

No additional patients accrued since PI PCS'd. Termination requested.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-102 REPORT DATE: 06/01/96 STATUS: Ongoing

TITLE: **The Risk of Hemorrhage in Patients with Interstitial Lung Disease Undergoing Transbronchial Lung Biopsy: An Analysis of Pulmonary Hypertension as a Risk Factor**

START DATE: 07/01/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Morris, Michael J.**

ASSOCIATE INVESTIGATOR: Peacock, Mark D.; Mego, David

DEPARTMENT/SERVICE: Med/Pulm Dis FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 52

### OBJECTIVES:

In a prospective manner this project will determine the incidence of clinically occult pulmonary hypertension in patients with interstitial lung disease. Subsequently, the rates of hemorrhage following transbronchial lung biopsy in patients with interstitial lung disease will be compared with regards to the presence or absence of clinically occult PH. We propose that PH detectable only by echocardiography does not increase the risk of hemorrhage during TBBx.

### TECHNICAL APPROACH:

The hypothesis to be tested is that PH, that is not clinically evident by physical exam and radiographic evaluation, but detectable by echocardiography does not cause increased hemorrhagic complications from transbronchial biopsies. Patients over the age of eighteen presenting to the Pulmonary Clinic for evaluation of ILD and who require bronchoscopy and transbronchial biopsies for diagnosis will be included in the study if they fulfill the criteria (outlined in protocol).

### PROGRESS:

Jun 96: 16 patients have been enrolled since Jan 95 to bring total to 52 patients. No adverse effects have been encountered. The study will be completed within the next 2 months with the entry of 2 more patients in the study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-034      REPORT DATE: 01/01/96      STATUS: Ongoing  
TITLE: Comparison of Fluorescent Bronchoscopy to White-Light Bronchoscopy in Detecting Lung Carcinoma

START DATE: 01/21/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Anders, Gregg T.

ASSOCIATE INVESTIGATOR: Blanton, HM

DEPARTMENT/SERVICE: Med/Pulm/Crit      FACILITY: BAMC

KEY WORDS: Fluorescent Bronchoscopy White-light Bronchoscopy

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

To determine any statistically significant increase in lung cancer diagnosis using fluorescent bronchoscopy as compared to white-light bronchoscopy performed on the same period. Patients will be selected from 3 groups for whom the medical literature has suggested a higher than usual rate of occurrence (or, in some cases, recurrence) of bronchogenic carcinoma--patients in whom lung cancer has been resected; patients diagnosed with head and neck cancer; and patients who smoke more than 2 packs of cigarettes daily.

### TECHNICAL APPROACH:

Patients will serve as their own controls via the white-light bronchoscopy. They will be selected from one of the following groups: 1. Patients with Stage I resected lung cancer without evidence of metastasis, referred from the Thoracic Surgery Service or the Medical Oncology Clinic to the Pulmonary Clinic; 2. Patients with surgically resected head and neck cancer without evidence of metastasis at the time of initial diagnosis, referred from the Otolaryngology Clinic; 3. Patients referred to BAMC Pulmonary Service of the Smoking Cessation Clinic who are currently smoking more than 2 packs of cigarettes per day with symptoms of cough or dyspnea.

### PROGRESS:

Jan 96: One patient has been enrolled thus far - equipment was not on-line prior to 15 Sep 94.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-105 REPORT DATE: 05/01/96 STATUS: Ongoing

TITLE: The Use of Albuterol in the Premedication of Patients with Chronic Obstructive Pulmonary Disease Undergoing Routine Flexible Fiberoptic Bronchoscopy

START DATE: 06/21/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Atkins, John

ASSOCIATE INVESTIGATOR: Peacock, Mark; Blanton, Herman

DEPARTMENT/SERVICE: Med/Pulm Dis FACILITY: BAMC

KEY WORDS: Albuterol, flexible fiberoptic bronchoscopy (FFB), nebulized

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 13

### OBJECTIVES:

To evaluate the effect of premedication with nebulized albuterol upon post-procedural complication rates in patients with chronic obstructive pulmonary disease (COPD) undergoing routine flexible fiberoptic bronchoscopy (FFB).

### TECHNICAL APPROACH:

Adult male and female patients with a clinical history consistent with COPD and with spirometric evidence of an obstructive ventilatory defect, that are to undergo a medically indicated bronchoscopic procedure. The criterion for a significant obstructive ventilatory defect is a difference of at least 9 between the predicted FEV<sub>1</sub>/FVC ratio and the actual FEV<sub>1</sub>/FVC ratio in women and a similar difference of 8% in men. All subjects will not use any inhaled bronchodilators four hours prior to the procedure.

### PROGRESS:

May 96: No new patients since last report due to PIs' rotations elsewhere . Plans are to resume intensely in July and hopefully enroll at least 40 patients by September 1996.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-110 REPORT DATE: 05/01/96 STATUS: Completed

TITLE: A Prospective Randomized Double-Blind Study Comparison of Flexible Fiberoptic Bronchoscopy with and without the Use of Preprocedure Sedation

START DATE: 06/28/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Bradley, James P.

ASSOCIATE INVESTIGATOR: Peacock, Mark D.

DEPARTMENT/SERVICE: Med/Pulm Dis

FACILITY: BAMC

KEY WORDS: Flexible Fiberoptic Bronchoscopy, respiratory depression, cardiac

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 30

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 30

### OBJECTIVES:

Over 50% of life threatening complications from flexible fiberoptic bronchoscopy are from the premedications given, and are primarily due to respiratory depression and cardiac arrhythmias. The majority of procedures are performed on an outpatient basis; therefore, cost containment from medications given, observation required, as well as the need for hospitalization are important. A prospective study is needed to compare outcomes with and without use of premedication during flexible fiberoptic bronchoscopy for tolerance and whether a significant time and cost savings can be realized.

### TECHNICAL APPROACH:

Subjects - male and female patients older than 18 years of age, who require routine bronchoscopy, will be asked to volunteer to participate in this study. After informed consent is obtained, patients will be randomized to two groups. The study group will be premedicated with atropine, 0.6mg, and versed, 0.07 mg/kg, intramuscularly. The control group will be given a placebo consisting of normal saline IM in equal volumes given the first group. Both groups will get the injection 30 minutes prior to the start of the procedure. The patient, the technician, and the bronchoscopist will be blinded to the premedication given.

### PROGRESS:

May 96: No side effects or complications encountered. Paper has been written and submitted to journal.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-139 REPORT DATE: 04/01/96 STATUS: Ongoing

TITLE: Do alveolar macrophages from emphysematous patients produce increased levels of proteases?

START DATE: 05/15/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Ouellette, Daniel R.

ASSOCIATE INVESTIGATOR: Merrill, Gerald

DEPARTMENT/SERVICE: Med/Pulm Dis

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To investigate the importance of alveolar macrophages and substances that they produce or secrete in the development of emphysema in people who smoke cigarettes. The specific substances to be the subject of this project are previously identified cysteine proteases that have elastolytic properties and peroxidase activity, which can lead to decreased levels of antiproteases. This will be a prospective study involving specimens isolated by bronchoalveolar lavage from about 50 patients and controls with a history of smoking and chronic respiratory illness. Results from these assays will be correlated with patient pulmonary function to discover if increased elastolytic activity or peroxidase activity is associated in an incremental fashion with increased severity of obstructive airway disease.

### TECHNICAL APPROACH:

This investigation is expected to demonstrate that alveolar macrophages isolated from patients with COPD contain a cysteine protease whose activity when quantitated, correlates directly with the degree of airflow obstruction that these patients have. Also expect to demonstrate that oxidase or peroxidase activity of intact macrophages correlates directly with the degree of airflow obstruction.

### PROGRESS:

Apr 96: Still working on developing the assays. Will be enrolling patients soon.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-059      REPORT DATE: 09/26/96      STATUS: Ongoing  
TITLE: Comparison of Selected criteria for Differentiating Pleural Effusion Exudates from Transudates

START DATE: 01/26/96      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Worley, Brian  
ASSOCIATE INVESTIGATOR: Peacock, M

DEPARTMENT/SERVICE: Med/Pulm Dis      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

To compare Light's criteria for separating pleural effusion exudates and transudates with recently proposed criteria involving effusion cholesterol, bilirubin, and serum-effusion albumin gradient.

TECHNICAL APPROACH:

Description of subjects/controls, design/methods and data collection are outlined in protocol.

PROGRESS:

Scheduled for review Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-062 REPORT DATE: 04/19/96 STATUS: Ongoing

TITLE: Evaluation of Exertional Dyspnea in the Active Duty Patient: An Analysis of Dyspnea Symptoms and the Utility of Clinical Testing

START DATE: 04/15/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Morris, Michael

ASSOCIATE INVESTIGATOR: Johnson, James; Grbach, Vincent; Johnson, Bryan;  
Nottestad, Sheri; Brassard, James

DEPARTMENT/SERVICE: Med/Pulm Dis FACILITY: BAMC

KEY WORDS: exertional dyspnea

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

In a prospective, blinded manner, we will determine the clinical utility of specific testing modalities in the evaluation of exertional dyspnea in a young active duty population. We will further determine, through the use of dyspnea scales and questionnaires, if there are specific clinical presentations to the exertional symptoms manifested by the patients for different diseases. Proposed that certain routine tests will be of low yield due to the decreased pretest likelihood in this group of patients. Overall, expect to prove that a history and physical exam and testing available at the MEDDAC are sufficient to rule out medical causes for exercise intolerance. In the remaining patients, we will probably demonstrate statistical evidence of deconditioning both by exercise testing and by questions relating to exercise before and since entrance into active military service.

### TECHNICAL APPROACH:

Medical application, status, technical approach including description of subjects and controls, design and methods, and further details are included in protocol.

### PROGRESS:

No report available as of this date. Annual review due Feb 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-066 REPORT DATE: 09/26/97 STATUS: Ongoing

TITLE: Prevalence of Obstructive Sleep Apnea in Patients with Severe Gastroesophageal Reflux Disease

START DATE: 05/08/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Worley, Brian D.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Pulm Dis FACILITY: BAMC/WHMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the prevalence of obstructive sleep apnea in those patients with recalcitrant gastroesophageal reflux. In this study,, those patients followed in the Gastro Clinic for gastroesophageal reflux disease with a DeMeester score of greater than 30 by ambulatory 24 hour pH recording will undergo overnight polysomnograms with 24 hour pH monitoring to determine if obstructive sleep apnea is significant contributor to reflux events.

### TECHNICAL APPROACH:

Study design, methods, analysis, etc are outlined in protocol.

### PROGRESS:

Due annual review Mar 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-092      REPORT DATE: 06/01/96      STATUS: Ongoing

TITLE: Comparison of the Work of Breathing Between CPAP and flow-by Triggering During weaning from Mechanical Ventilation

START DATE: 07/02/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Morris, Michael J.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Med/Pulm Dis      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Two different methods of weaning patients from prolonged mechanical ventilation, continuous positive airway pressure and flow-by triggering, will be compared in the same patient. Both are weaning methods where patients breathe spontaneously with minimal ventilator assistance to determine their ability to be safely removed from mechanical ventilation. Measuring the work of breathing with the use of these two different methods in the same patient can help differentiate which mode may assist weaning and earlier extubation of patients on prolonged mechanical ventilation.

### TECHNICAL APPROACH:

Description of subjects/controls, experimental design/methods and other specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Mar 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-125      REPORT DATE: 09/18/96      STATUS: Ongoing

TITLE: **The Acute and Chronic Effects of Heliox and BIPAP on Exercise Tolerance in Patients with Chronic Obstructive Pulmonary Disease**

START DATE:      /      /      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: **Johnson, James E.**

ASSOCIATE INVESTIGATOR: Anders, Adams-Dramiga, Sine, Larson

DEPARTMENT/SERVICE: Med/Pulm Dis      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This study will address the issue of whether unloading the respiratory system mechanically in patients with COPD will acutely increase their exercise tolerance. It will also address the issue of whether unloading the respiratory system in a similar manner during an exercise oriented pulmonary rehabilitation program will result in greater than usual increases in exercise ability.

### TECHNICAL APPROACH:

The hypotheses, experimental design and specifics are outlined in protocol.

### PROGRESS:

Annual review is due in 1997.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-126 REPORT DATE: 09/18/96 STATUS: Ongoing

TITLE: Reduction Pneumoplasty for the Treatment of Emphysema

START DATE: 09/03/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Ouellette, Daniel R.

ASSOCIATE INVESTIGATOR: Anders, Cohen, Johnson J.

DEPARTMENT/SERVICE: Med/Pulm Dis FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To investigate the effects of reduction pneumoplasty for the treatment of emphysema, to establish guidelines for patient selection for the procedure, and to determine the associated surgical morbidity and mortality. This will be a prospective, pilot study involving approximately 25 patients which may be subsequently expanded depending upon the results. Subjects will be patients with chronic obstructive pulmonary disease from the pulmonary clinic with substantial dyspnea on exertion (or resting dyspnea) and objective evidence of severe obstructive lung disease demonstrated by spirometry on maximum medical therapy.

### TECHNICAL APPROACH:

Patients will be enrolled from the pulmonary clinic at BAMC. All patients with severe COPD may be considered for enrollment. Although some centers have used specific enrollment criteria for experimental programs in reduction pneumoplasty, the applicability of this procedure is not known, and it may be prudent at this time to have guidelines rather than strict criteria.

### PROGRESS:

Annual review is due in April 1997.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-032 REPORT DATE: 01/29/96 STATUS: Ongoing

TITLE: Effects of Salsalate, a Non-acetylated Salicylate, on Bleeding Time and Platelet Function in Patients with Osteoarthritis

START DATE: 01/02/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Swank, Jonathan T.

ASSOCIATE INVESTIGATOR: Older, Battafarano

DEPARTMENT/SERVICE: Med/Rheum

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if salsalate, a non-acetylated salicylate, affects platelet function as measured by bleeding time, platelet aggregation and thromboxane B2 levels. A single-blind, controlled, cross-sectional cohort design will be utilized to examine this question in a hospital-based rheumatology clinic population.

### TECHNICAL APPROACH:

Hypothesis: Salsalate, a non-acetylated salicylate, does not affect platelet function as measured by bleeding time, platelet aggregation and serum prostaglandin level in patients on chronic ( > 3 months) therapeutic doses (3000mg/day).

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-014 REPORT DATE: 09/01/96 STATUS: Completed

TITLE: Computer Simulation Modeling Applied to Capacity Management Decision Making in a Pediatric Ambulatory Clinic

START DATE: 10/01/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Odom, James D., AN

ASSOCIATE INVESTIGATOR: Richard

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To identify those factors that influence resource consumption and utilization in an ambulatory pediatric clinic; and 2. To develop and test a model of optimal capacity decision making through application of computer simulation. Using a time-series design with repeated measurements process, this study will be conducted in two phases. During Phase I, aim 1 will be addressed. During Phase II, a model that can be used for effective capacity management decisions will be developed and tested.

### TECHNICAL APPROACH:

Design, study site, procedure, computer simulation software, human subjects and other specifics are outlined in protocol.

### PROGRESS:

Oct 95: Study is nearing completion; final report forthcoming before end of year.

Sep 96: LTC Yoder reports that study is completed, abstract in file.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-003      REPORT DATE: 01/01/96      STATUS: Completed

TITLE: Evaluation of a Structured Physical Fitness Program for Pregnant Soldiers: Effects on Weight Gain, Blood Pressure, Lost Duty Time, Length of Labor, Infant Birth Weight, and Score on the First Army Physical Fitness Test (APFT) Post Delivery

START DATE: 11/08/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Wannersdorfer, Elizabeth

ASSOCIATE INVESTIGATOR: Gonzalves (Darnall)

DEPARTMENT/SERVICE: Nursing

FACILITY: DACH/FAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 100

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 100

### OBJECTIVES:

To determine whether pregnant soldiers participating in a structured exercise program will have less weight gain, less change in blood pressure, shorter length of labor, higher birth weight babies, less lost duty time, and better ability to pass their first physical fitness test than do pregnant soldiers who do not participate in a structured program. The long term objective is the development of military policy for physical training for pregnant soldiers, contributing to healthier soldiers, healthier babies, and improved military readiness.

### TECHNICAL APPROACH:

Study design, medical application, plan and further details are outlined in protocol.

### PROGRESS:

Nov 95: Enrollment is taking longer than originally anticipated but the goal should be met. Basic data has been loaded into the computer but no significant results are available at this time. At this time have sixty-six percent of the total enrollment. Three have had to drop out of the study for reasons unrelated to the study. Data will not be analyzed until the study is completed.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-014      REPORT DATE: 01/01/96      STATUS: Completed  
TITLE: Alternative Pain Therapy & Anxiolysis in Surgery

START DATE: 01/13/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Reilly, Maureen

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

To examine an alternative method for sedating patients while the ophthalmologist is anesthetizing the eye. this method of sedation has been studied in a smaller number of patients in another project. This project will be done on approximately 116 patients.

### TECHNICAL APPROACH:

Study design/method, specific aim, background and significance and further details are included in protocol.

### PROGRESS:

Jan 96: Study was completed with favorable results but they were not furnished at this reporting time.

# DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-035

REPORT DATE: 02/08/96

STATUS: Completed

**TITLE: Identification of Family Strengths and Needs Using the Q-Sort Process**

START DATE: 02/01/95

ESTIMATED COMPLETION DATE:        /    /

PRINCIPAL INVESTIGATOR: **Chandler, Patrice E.**

ASSOCIATE INVESTIGATOR:   Feinberg, Majorie OTR FAMC; Flynn, Linda, PhD JFK Cen for  
                                  Dev Disabilities

DEPARTMENT/SERVICE:      Nursing

FACILITY: BAMC

**KEY WORDS :**

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 21

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 21

**OBJECTIVES:**

Approximately 30 to 40 parents or sets of parents will be recruited who meet inclusion criteria (i.e., have an infant(s) currently in the NICU for greater than 10 days duration whose diagnosis meets the criteria for an IFSP under the guidelines outlined in PL99-457). The optional nature of participation will be stressed in describing the project to parents.

TECHNICAL APPROACH:

The following demographic information will be collected: maternal data, infant data, sibling data, family socioeconomic data and hospitalization data.

PROGRESS :

Feb 96: Analysis is in progress. Preliminary data findings indicate that families have strong Instrumental needs (information about their babies, and how they can help them). Further research should focus on families after discharge. Potential research questions - If families needs were met prior to discharge, was the transition to home less stressful? If families needs were identified and met, were there fewer repeat hospitalizations? Do the same needs apply to families of adult patients? (LTC Yoder)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-040      REPORT DATE: 02/08/96      STATUS: Ongoing  
TITLE: An Exploration of Quality of Life Experienced by People with Cancer

START DATE: 03/20/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Yoder, Linda H.

ASSOCIATE INVESTIGATOR: O'Rourke, Begley

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 105

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 105

### OBJECTIVES:

In the last decade there has been a proliferation of new drugs and strategies for intensifying the treatments used to combat cancer. These aggressive treatment strategies also have led to increasing toxicities experienced by patients. Often, cancer therapies are evaluated solely on the basis of increased survival. It is critical that outcomes for cancer patients move beyond morbidity and mortality statistics to include information about quality of life during and after treatment.

### TECHNICAL APPROACH:

Study design, methods and specifics are outlined in protocol. 1LT Sandra Begley (original PI) was transferred to Fort Hood. Currently, the PI intends to submit a continuation request by the 2 Apr 96 deadline for Tri-Service Nursing grants. This continuation will be requested because patient accrual is slowing and although I anticipate that we will have the sample size specified in the study, we may need additional support for data entry and analysis (LTC Yoder).

### PROGRESS:

Feb 96: This study was funded by Tri-Service Nursing for \$95,211. The study began on 20 Oct 95 and currently have 105 patients enrolled. Approximately 50 of these subjects have completed the second of 4 iterations of instrument completion.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-041      REPORT DATE: 02/08/96      STATUS: Terminated

TITLE: A Comparative Study of Parental Stress in the Neonatal Intensive Care Unit

START DATE: 03/20/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Chandler, Patrice

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Nursing      FACILITY: BAMC

KEY WORDS: Parental stress; pre-term infants

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The specific aims of this study of parents with preterm infants requiring neonatal intensive care, are to determine: 1. levels of parental psychosocial stress during the initial phase of neonatal intensive care experience; 2. effectiveness of a cognitive intervention on parental knowledge about the care of the preterm infant; 3. effectiveness of a cognitive intervention on parental psychosocial stress during the neonatal intensive care experience; 4. effectiveness of a cognitive intervention on parent-infant interaction at the time the infant meets discharge criteria; 5. effectiveness of a cognitive intervention on parental psychosocial stress at the time the infant meets discharge criteria.

### TECHNICAL APPROACH:

Research design and specifics are outlined in protocol.

### PROGRESS:

Feb 96: This study was submitted to Tri-Service Nursing Research Program for funding. The study was not funded and was never began. This study will not be resubmitted, therefore the protocol may be terminated. (LTC Yoder)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-042      REPORT DATE: 02/08/96      STATUS: Ongoing

TITLE: **Determinants of Health-Promoting Behaviors of Patients with Chronic Stable Angina**

START DATE: 03/20/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Hodge, Nancy S.**

ASSOCIATE INVESTIGATOR: Khan, Nancy

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

Healthy male and female adult volunteers aged 18 to 50 will be recruited for participation. It is estimated that a total of 24 subjects (8 per experimental group) will be needed to obtain significance under this study's design (see Design & Methods in protocol).

### TECHNICAL APPROACH:

Methods and specific details are outlined in protocol.

### PROGRESS:

Feb 96: This study is a nursing addition to Dr. Sheri Nottestad's study "Cardiac Risk Evaluation with Exercise, Echocardiography Stress Testing. LTC Hodge began accruing patients in Oct 95. Three patients were recruited, one suffered a myocardial infarction and therefore currently 2 patients on study. Request protocol be maintained in an open status and status of funding will be furnished. (LTC Yoder)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-077      REPORT DATE: 01/01/96      STATUS: Ongoing

TITLE: Pressure Ulcers: Patient Outcomes on a Kinair Bed or EHOB Mattress

START DATE: 02/27/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Cobb, Gladys A.

ASSOCIATE INVESTIGATOR: Yoder, Harrington, Perdue

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 12

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 12

### OBJECTIVES:

To compare a low air loss, pressure relieving rental bed to a waffle pressure relieving air mattress overlay. Subjects will consist of patients considered to be at high risk for pressure ulcer development. More specifically, the following research questions will be addressed: 1. What is the demographic profile of the patient at high risk for pressure ulcer development in a large military acute care setting? 2. Is there a difference in the number of pressure ulcers or the seriousness of pressure ulcers that develop among high risk patients when Kinair low air loss specialty beds are used compared to EHOB waffle air mattress overlays? 3. Is there a difference in length of stay, related to pressure ulcers, among high risk patients when placed on the Kinair bed compared to the EHOB waffle air mattress? 4. Is there a difference in cost expenditure related to pressure ulcer development when Kinair low air loss specialty beds compared to EHOB waffle air mattresses are used?

### TECHNICAL APPROACH:

Background/significance, definition/physiolog, risk factors, research design/methods and further specifics are outlined in protocol.

### PROGRESS:

Feb 96: Several potential patients have been lost for various reasons. Since difficulty is encountered with accrual of high risk surgical patients for this study, request was made to amend this protocol. The addition of high risk medical patients to the current patient population of high risk surgical patients would help in accruing greater numbers. This patient population will meet the same criteria and will have the same needs in regards to pressure ulcer prevention. Methods and design of the study will remain the same and the data between groups should be similar.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-078      REPORT DATE: 02/08/96      STATUS: Ongoing

TITLE: An exploration of Quality of Life experienced by People with Chronic Obstructive Pulmonary Disease

START DATE: 02/27/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Anderson, Susan E.

ASSOCIATE INVESTIGATOR: Yoder, Perdue, Coscarelli

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The life expectancy of most adult Americans has markedly increased with the advent of advanced medical technology. A significant consequence of the increase in longevity is a shift in the nature of prominent diseases from acute chronic. There has been a growing awareness of the inadequacy of the traditional morbidity and mortality data in reflecting health status in the chronic patient population. We can no longer afford to assume that medical interventions are producing desired result. The focus of care of the chronically ill has shifted from cure to care and rehabilitation. As patients with chronic and disabling diseases are offered a variety of treatment choices, the challenge becomes how to choose an option that provides the greatest pulmonary disease, quality of life may be the most important health outcome to consider.

### TECHNICAL APPROACH:

Further specifics are outlined in protocol.

### PROGRESS:

Feb 96: This study was submitted to the Tri-Service Nursing Research grant program, but was not funded. This proposal will be submitted again this year (by the 2 Apr 96 deadline), with an appropriate response the reviewers' critiques. This study was never started because of the lack of funding. Request protocol be maintained in an open status and update to funding status will be provided. (LTC Yoder)



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-079      REPORT DATE: 02/08/96      STATUS: Terminated  
TITLE: A Comparison of Two Totally Implanted Venous access Devices

START DATE: 02/27/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Noble, Lilly J.

ASSOCIATE INVESTIGATOR: Yoder, Martin, Mancoff, O'Rourke, Perdue

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS: Implanted venous devices

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The overall aim of this study is to use clinical research to problem solve a recurrent quality assurance issue concerning the LifePort implantable venous access device. The specific aim is to evaluate an implanted venous access device (IVAD) with a revolutionary new design, the OmegaPort by Norfolk Medical, compared to the standard IVAD, the LifePort by Strato/Infusaid, currently in use. To this end the following hypotheses have been generated: 1. The OmegaPort will have a lower incidence of complications than the LifePort. 2. Over a period of nine months, total costs associated with the OmegaPort will be less than total costs associated with the LifePort. 3. Patient satisfaction regarding the IVAD will be higher for the OmegaPort.

### TECHNICAL APPROACH:

Further specifics are outlined in protocol.

### PROGRESS:

Feb 96: This study was submitted to the Tri-Service Nursing Research Program for funding. Funding was denied. The PI has been transferred to Walter Reed Army Medical Center. The study was never started. The study may be terminated. (LTC Yoder)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-080 REPORT DATE: 02/01/96 STATUS: Terminated

TITLE: Coronary blood Flow Hemodynamics in Patients with Left Bundle Branch Block

START DATE: 02/27/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Bauch, Terry D.

ASSOCIATE INVESTIGATOR: Zimring, Campos, Ebersole, Wright, Mego

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. Compare the Coronary flow Reserve of the Left Anterior Descending (LAD), First Septal Perforator (FSP) and Circumflex (CFX) coronary arteries in patients with isolated Left Bundle Branch Block (LBBB). 2. compare the CFR of the LAD in these patients with normal controls. 3. Compare the coronary flow response of the LAD, FSP and CFX to heart rate and Dobutamine stimuli in patients with LBBB...

### TECHNICAL APPROACH:

Include patients over 18 years old with isolated LBBB who will undergo cardiac catheterization for clinical indications. Exclusions and further specifics outlined in protocol.

### PROGRESS:

Feb 96: Study terminated - not technically feasible.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-081      REPORT DATE: 02/08/96      STATUS: Ongoing  
TITLE: An Exploration of Quality of Life experienced by People with Congestive Heart Failure

START DATE: 02/27/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Hodge, Nancy S.

ASSOCIATE INVESTIGATOR: Yoder, Perdue, Coscarelli

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 12

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 12

### OBJECTIVES:

As a disease primarily of the elderly, the number of patients with heart failure is ever-increasing with the "graing of America" and therepeutic advances to decrease mortality rates. In spite of increasingly sophisticated medical care, mortality rates are highest for the heart failure patient population.

### TECHNICAL APPROACH:

Research design/methods, and further specifics are outlined in protocol.

### PROGRESS:

Feb 96: This study was submitted to the Tri-Service Nursing Research grant program, but was not funded. This proposal will be submitted again this year (by the 2 Apr 96 deadline) with an appropriate response the reviewers' critiques. In order to strengthen the grant submission this year, LTC Hodge began the study as a pilot in Dec 95 and currently has 12 patients on the study. (LTC Yoder)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-121 REPORT DATE: 07/01/96 STATUS: Ongoing

TITLE: Comparison of the Relationship Between Patient Height vs the Vertebral Column Length and the Level of Subarachnoid Sensory Blockade Produced Using 0.75% Bupivacaine

START DATE: 08/11/95 ESTIMATED COMPLETION DATE: 08/31/96

PRINCIPAL INVESTIGATOR: Bequette, Bonnie

ASSOCIATE INVESTIGATOR: Bruner, Kurtz, Jones

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC/DACH

KEY WORDS: Vertebral column length, bupivacaine, sensory blockade

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 87

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 87

### OBJECTIVES:

To answer the following research question: What is the correlation between patient height versus the length of the vertebral column and the level of subarachnoid sensory blockade produced using 0.75% bupivacaine?

### TECHNICAL APPROACH:

The study will include 85 male or female adult inpatient volunteers. The study drug is Bupivacaine.

### PROGRESS:

Jul 96: Currently 87 patients have been enrolled in the study and we have been operating in accordance with the approved research protocol. None of the subjects have encountered any adverse effects related to the study. We are in the process of over sampling by 13 patients to ensure 85 subjects are available for data analysis. Data analysis will begin in August.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-129      REPORT DATE: 07/01/96      STATUS: Ongoing  
TITLE: Fatigue Experienced by Bone Marrow Transplant Patients: An Exploratory Study

START DATE:      /      /      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Yoder, Linda

ASSOCIATE INVESTIGATOR: Connelly, Johnson

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 11

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 11

### OBJECTIVES:

Oncology healthcare providers and cancer patients agree that fatigue is highly prevalent among those being treated for cancer or recovering from a cancer illness. However, little is known about the fatigue experience from the perspective of the patient. This perspective is critical because fatigue is a subjective experience.

### TECHNICAL APPROACH:

Detailed specifics are outlined in protocol.

### PROGRESS:

Jul 96: LTC Yoder has informed DCI that the study has been condensed to:  
(1) Narrowed to consist only of bone marrow transplant patients; (2)  
Conducting an initial interview with the bone marrow transplant patient, (3)  
Collecting demographic data as described in protocol, and (4) Conducting the  
second interview with the patient 30 days after discharge. It will be  
conducted only in the BAMC Bone Marrow Transplant Unit and will consist of  
approx 30 patients over the next year. Name of study was slightly changed to  
reflect the population restriction.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-131 REPORT DATE: 06/01/96 STATUS: Withdrawn

TITLE: Outcomes Management: A Mechanism for Predicting Post-Operative Wound Infections

START DATE: 07/17/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Blanke, Julie Ann

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Nosocomial infections following open heart surgical procedures remain a potentially serious complication to this procedure. Beyond increasing human suffering, postoperative wound infections frequently result in an increased length of stay and a financial loss to the hospital. There are inaccuracies in current database systems. In terms of its accuracy, the data is questionable. The purpose of this grant is to use steps commonly associated with outcomes management to: a) develop a computerized database that will be used to track wound infection in this patient population, b) define accurate wound infection rates for the cardiothoracic surgery service based on the site of the infection and c) identify patient characteristics that may increase the risk of surgical wound infection.

### TECHNICAL APPROACH:

A non-experimental, descriptive design is proposed to examine the risks of post-operative wound infections for open heart surgery patients. The sample will consist of all patients presenting to BAMC between 1 Jan 96 and 31 Aug 96 for cardiothoracic surgery. Inclusion criteria are: 18 years of age or older, undergoing open heart surgery, able to speak, read and write English, and able to give informed consent. Based on a power analysis, using a power of 0.80, a medium effect size (.30) and a .05 level of significance with five degrees of freedom, a sample size of 200 patients will be needed. Further data collection/analysis, entry procedures, etc., are outlined in protocol.

### PROGRESS:

Jun 96: This study was not funded. No patients have been enrolled. It can be withdrawn.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-134 REPORT DATE: 07/01/96 STATUS: Ongoing

TITLE: Staged-Based Smoking Cessation Project

START DATE: 09/11/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Foley, Beth

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC1/DAH/Ft

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 621

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 621

### OBJECTIVES:

a. To devise a method to integrate inprocessing and health risk appraisal (HRA) systems on Army installations in order to: determine the prevalence of smoking among newly-arrived soldiers; analyze smoking prevalence by demographic categories and other health-related behaviors and risk factors and identify a cohort for longitudinal study of smoking behavior and smoking cessation. b. Among soldiers who are identified as smokers, to develop a method to assess intention to quit smoking. c. To evaluate the impact of an adaptive smoking cessation strategy on smoking rates in the identified population.

### TECHNICAL APPROACH:

Medical application; status; plan, analysis and further specifics are outlined in protocol.

### PROGRESS:

Jul 96: The project began enrolling soldiers in Apr 95. Initially, Ft Hood was pilot testing surveys and actually began enrolling soldiers in Apr 96. As of 31 May they have enrolled 621 soldiers. Analysis of the data is currently underway at USUHS. More details can be obtained from LTC Ken Hoffman (PI) at DSN 295-2642.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-013      REPORT DATE: 11/01/96      STATUS: Ongoing

TITLE: Functional Status and Quality of Life Experienced by Women with Breast Cancer

START DATE: 12/05/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Yoder, Linda

ASSOCIATE INVESTIGATOR: Johnson, Jean

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Primary purpose is to systematically examine functional status and quality of life issues for improved holistic treatment of the breast cancer patient. Specifically, this study will address the following research questions: 1. What is the variation in functional status and quality of life experienced over time by women with breast cancer? 2. What components of functional status and quality of life are rated as most important by the women? 3. What is the relationship between certain demographic and treatment characteristics, such as age, marital status, and type of treatment regimen, to functional status and quality of life scores?

### TECHNICAL APPROACH:

Conceptual framework, research design and methods and further specifics are outlined in protocol.

### PROGRESS:

Nov 96: This study was never started because it was not funded by the Breast Cancer Research Program. Plan to rework this study based on the critique. Request study be kept on file in an inactive status (LTLC Yoder).



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-044      REPORT DATE: 06/01/96      STATUS: Completed

TITLE: **Aftereffects of Perineal Injury Sustained During Childbirth**

START DATE: 02/07/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Altenburg, Susan**

ASSOCIATE INVESTIGATOR: Fort Carson

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC/Ft Carson

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if there are any long term, adverse sequelae among postpartum women who sustained 3rd or 4th degree perineal lacerations during delivery, when compared to a control group who delivered vaginally over intact perineums.

### TECHNICAL APPROACH:

Plan is to gather 50 subjects for the group with intact perineums and a total of 50 subjects for the group with either 3rd or 4th degree lacerations. Duration of study anticipated to last approximately six months, data collection expected to take one month, depending upon how successful in reaching people on the phone.

### PROGRESS:

Jun 96: Completed - A descriptive telephone survey was used to determine whether women who sustained anal sphincter rupture during childbirth suffered from any long-term, adverse sequelae. Chart review and telephone interview were conducted with 62 primiparas, 31 of whom sustained anal sphincter rupture and 31 of whom did not. Findings of this study demonstrate a high correlation (30/31) between midline episiotomy and anal sphincter rupture. However, factors that may have influenced the accoucheur's decision to perform episiotomy, such as nulliparity and estimated infant birth weight, also put the perineum at greater risk of rectal injury.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-069 REPORT DATE: 09/01/96 STATUS: Completed

TITLE: The Effects of Information Provided in a Pulmonary Rehabilitation Booklet on Improving the Pulmonary and General Functional Status of Adult Patients with Chronic Obstructive Pulm Disease

START DATE: 05/10/96 ESTIMATED COMPLETION DATE: 07/31/96

PRINCIPAL INVESTIGATOR: Suentzenich, Bonnie

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess the effectiveness of information provided in a pulmonary rehabilitation booklet on improving the pulmonary and general functional status of adult patients with COPD who are treated in a military health care setting.

### TECHNICAL APPROACH:

Subjects must be 18 years of age or older, both male and female subjects will be recruited. Design for the study will be a quasi-experimental two group pre-test/post-test design. A convenience sample of a minimum of 52 subjects who meet the study criteria will be recruited. The subjects will then be assigned randomly to either the control or experimental group.

### PROGRESS:

Aug 96: Notification was received from CPT Bonnie L. Pappas, AN, Graduate Nursing Program, that study has been completed. It is believed that future research with a larger sample size and different tool would yield favorable results for the pulmonary rehabilitation booklet. Subjects involved reported no adverse reactions, nor problems during the project.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-099      REPORT DATE: 07/15/96      STATUS: , Ongoing  
TITLE: Postoperative Oxygen Desaturation Following Spinal Anesthesia

START DATE: 08/08/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Nichols, Vicki J.

ASSOCIATE INVESTIGATOR: Magoulick, McCormick, Haynie, Simpson

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC1/DACH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine, if during transport from the operating room to the post anesthesia care unit, stable adult surgical patients (ASA I and II patients) experience oxygen desaturation following spinal anesthesia with midazolam sedation.

### TECHNICAL APPROACH:

To determine if significant oxygen desaturation occurs during transport from the OR to the PACU, a descriptive study using a convenience sample will be conducted. Inclusion/exclusion criteria and further details are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-100 REPORT DATE: 07/15/96 STATUS: Ongoing

TITLE: Quality of Life Experienced by People with End Stage Renal Failure

START DATE: 08/08/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Minton, Amelia

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Nursing FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To systematically examine quality of life issues experienced by patients with end stage renal disease, treated in a military healthcare facility.

### TECHNICAL APPROACH:

Study consists of a descriptive, repeated measures design, consisting of the administration of several quantitative instruments that will be administered initially at the time of consent and then at three month intervals X3 (total of four administrations).

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-123 REPORT DATE: 08/26/96 STATUS: Ongoing

TITLE: Drawing Coagulation Studies from a Normal Saline Venous Access Device in Heparinized Patients

START DATE: 08/26/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Powers, Jill M.

ASSOCIATE INVESTIGATOR: Pfanner

DEPARTMENT/SERVICE: Nursing

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This pilot study will answer the following research question: What is the amount of blood that should be discarded from a Normal Saline Venous Access Device on heparinized patients to obtain an accurate aPTT result?

### TECHNICAL APPROACH:

This pilot study consists of quasi-experimental, prospective design. A convenience sample will be used. The patient's venipuncture aPTT result will act as the control. Population, termination, data collection and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jun 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-082 REPORT DATE: 03/01/96 STATUS: Completed

TITLE: Simulation of Cervical Diameter Measurements: An Appraisal of Accuracy

START DATE: 05/14/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Phelps, John Y.

ASSOCIATE INVESTIGATOR: Smyth, Michael; Higby, Kenneth

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 123

### OBJECTIVES:

It has been proposed that incidences of PDPH with large bore catheters and needles and CSA is 70%. This study will theoretically lower this incidence by using a smaller needle (26 gauge) and tight fitting catheter (24 gauge) to reduce CSF leakage and will avoid complications of cauda equina syndrome by avoiding the use of a microcatheter, 5% lidocaine and any hyperbaric solutions. Patient evaluation, symptoms and specifics are outlined in protocol.

### TECHNICAL APPROACH:

Specifics outlined in protocol.

### PROGRESS:

Mar 96: Dr. Phelps has been reassigned to Fort Leonardwood. It was determined accuracy to be about 90% when allowed for an error of plus-minus 1 cm and no difference in accuracy between providers with different levels of experience. Dr. Smyth reported that study has been completed and paper published.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-030      REPORT DATE: 01/01/96      STATUS: Ongoing  
TITLE: Comparison of Anti-Hypertensive Agents for Hypertensive Emergencies in Pregnancy: A Pilot Study

START DATE: 01/14/94      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Higby, Kenneth  
ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Ob-Gyn      FACILITY: BAMC

KEY WORDS: Labetalol, clonidine, diazoxide, nifedipine  
NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

Since Apresoline is no longer being manufactured by Ciba-Geigy it is necessary to look at alternative forms of therapy for hypertensive emergencies in pregnancy. Desire to determine which agent (labetalol, clonidine, diazoxide, nifedipine) is most effective and has the least adverse effects upon patients. This has not been evaluated to date.

### TECHNICAL APPROACH:

Study design, study outcome monitors, sample size, subject population, etc. outlined in protocol.

### PROGRESS:

Jan 96: Only enrolled 2 subjects to date. Have had very few patients with severe hypertension. There have been no adverse effects to either patient.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-045      REPORT DATE: 02/20/96      STATUS: Completed

TITLE: Timing the Postcoital Test: Use of a Home Urinary LH Test Vs Traditional Methods

START DATE: 02/07/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Marconi, Mark

ASSOCIATE INVESTIGATOR: Gehlbach

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if use of a home urinary LH test improves the accuracy of timing the postcoital test, compared with traditional timing methods such as BBT charts & menstrual history.

### TECHNICAL APPROACH:

This study is designed to test whether home urinary LH determination improves the timing of postcoital testing, as compared with BBT charts and menstrual history. The patients to be studied will be infertile couples presenting to BAMC E&I clinic for initial infertility evaluation. Female subjects included will be between the ages of 18 & 40 with regular cycles with menses every 21-35 days and have ovulation confirmed by a d21 progesterone level >4 ng/ml. Exclusion criteria will include treatment with clomid or pergonal, lower genital tract infection, oligo-or azospermia, cervical anomalies, prior cervical surgery, & history of cervical factor infertility. The number of subjects required is 25. Further details in protocol.

### PROGRESS:

Feb 96: PI has been reassigned to Fort Bragg. Associate PI has also left. No one else interested in pursuing study. No subjects enrolled. (Dr. Higby)



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-050

REPORT DATE: 02/15/96

STATUS: Ongoing

TITLE: The Effect of Subcutaneous Terbutaline Therapy on Glucose Tolerance in Pregnancy as Assessed by a Modified Bergman's Minimal Model

START DATE: 02/07/94

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: McCoy, Craig E.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Ob-Gyn

FACILITY: BAMC

KEY WORDS: Terbutaline, pathophysiologic, terbutaline-induced

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 7

### OBJECTIVES:

To elucidate the pathophysiologic effects of terbutaline-induced changes in carbohydrate metabolism.

### TECHNICAL APPROACH:

Hypothesis is that subcutaneous Terbutaline has no significant effect on glucose metabolism.

### PROGRESS:

Feb 96: Need to enroll more patients and plan to continue at Wilford Hall Med Cen.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-092      REPORT DATE: 02/26/96      STATUS: Terminated

TITLE: Sterilization Regret in a Military Population

START DATE: 04/11/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thornton, Stacey

ASSOCIATE INVESTIGATOR: Gehlbach, Dan; Gehlbach, Lauren

DEPARTMENT/SERVICE: OB-Gyn      FACILITY: BAMC

KEY WORDS: Sterilization, tubal ligation reversal

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 150

### OBJECTIVES:

Among women in a military population who seek reversal of tubal ligation, to determine what factors they identify as responsible for their desire to overturn a permanent procedure.

### TECHNICAL APPROACH:

A questionnaire will be administered to three groups of women. It will have 17 questions from 5 different categories. It will contain no patient identifiers and the patients will be counseled that their responses will not influence their medical care or chance for sterilization reversal. Further specifics and statistic input is outlined in protocol.

### PROGRESS:

Mar 96: Dr. Thornton requests study be shown as terminated. Did not have quite enough subjects when remainder of staff left and study had to be dropped.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-047      REPORT DATE: 06/19/95      STATUS: Terminated

TITLE: **Influence of Parenteral Progesterone Administration on the Prevalence and Severity of Mastodynia in Active Duty Servicewomen**

START DATE: 03/20/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Anderson, Jeff**

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 697

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 314

### OBJECTIVES:

A study questionnaire will be distributed to approximately 6% of active duty service women in the US between ages of 18 and 44 in a multi-institutional cross-sectional study comparing women receiving parenteral progesterones (medroxyprogesterone acetate or levonorgestrel) with a control group. The specific aims are: 1. Assess the efficacy of progesterones in the prevention and treatment of mastodynia. 2. Determine the prevalence and quantitative and severity of mastodynia among active duty service women. 3. Quantitate the impact of mastodynia on productivity and military readiness. 4. Assess whether health care providers are meeting the expectations of women with mastodynia.

### TECHNICAL APPROACH:

Approximately 30% of women presenting to surgical breast clinics present for symptoms of breast pain. While approximately 85% of these women are adequately managed by reassurance after a thorough evaluation, 15% will find that the breast pain poses intolerable life-style limitations. Therapies for intractable mastodynia are generally directed at altering the hormonal milieu of the breast, but none is completely reliable and are currently under close scrutiny. Further specifics are outlined in the protocol.

### PROGRESS:

Mar 96: PI has left DACH and the Army. No one there is aware of the study or has any input to furnish, therefore consider it terminated.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-132      REPORT DATE: 01/01/96      STATUS: Ongoing  
TITLE: Pertussis Immunity in an Obstetric Population

START DATE: 09/01/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Heim, Bradley K.

ASSOCIATE INVESTIGATOR: Higby, Eaton, Staten, Merrill

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 200

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 200

### OBJECTIVES:

The purpose of the study is to determine the immune status to Pertussis in a sample of 600 obstetrical patients between the ages of 18 and 45.

Enzyme-linked immunosorbent assay (ELISA) techniques will be used to measure the presence or absence of serum IgG antibodies to purified pertussis toxin.

### TECHNICAL APPROACH:

This is a prevalence study to report the immune status of an obstetric population. We will determine the presence or absence of IgG immunoglobulin antibodies using purified Bordatella pertussis toxin as the antigen in the sera of consecutive pregnant women presenting for care at BAMC and University Hospital. Anticipate the enrollment of approximately 600 patients.

### PROGRESS:

Jan 96: Samples of 200 patients have been collected but will not be run until enrollment completed.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-018 REPORT DATE: 01/05/96 STATUS: Ongoing

TITLE: An Evaluation of Pain Perception and Clinical Outcome in Patients Undergoing Amniocentesis with and without Local Anesthesia

START DATE: 12/14/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Ventura-Braswell, Ada

ASSOCIATE INVESTIGATOR: Higby

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This study will be a retrospective study in which flow waves derived from a three element non-linear Windkessel model<sup>2</sup> are compared to directly recorded electromagnetic flow/velocity waveforms. Details including data analysis included in protocol.

### TECHNICAL APPROACH:

This will be a prospective randomized study. All patients undergoing an obstetrically indicated amniocentesis will be eligible for inclusion. Patients will be approached and asked to participate in the study by one of the investigators. The only exclusion criteria would be a known hypersensitivity to the local anesthetic (1% lidocaine). Further specifics outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Dec 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-034 REPORT DATE: 01/29/96 STATUS: Ongoing

TITLE: Does intraoperative infiltration with local anesthesia decrease postoperative pain?

START DATE: 01/02/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Roell, Stephanie

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC/WHMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if the intraoperative administration of 0.25% bupivacaine (marcaine) in the abdominal incision of patients undergoing laparotomy decreases postoperative pain and narcotic use.

### TECHNICAL APPROACH:

If the use of wound infiltration with local anesthesia can decrease postoperative pain and narcotic use, then patients will be able to ambulate and increase physical activity sooner. By decreasing narcotic use patients will have decreased postoperative morbidity associated with inactivity and narcotic use (i.e., ileus, sedation, nausea, vomiting, respiratory depression, etc). Status, hypothesis, project design and further details are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-036      REPORT DATE: 01/29/96      STATUS: Ongoing  
TITLE: Evaluation of Self-Monitored Blood Glucose Levels in Post-Partum Class A-2 Gestational Diabetics

START DATE: 01/15/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Whitcomb, Bradford P.

ASSOCIATE INVESTIGATOR: Higby

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This prospective study is designed to observe blood glucose levels of insulin-dependent gestational diabetics for six weeks post-partum. Currently there is no treatment or monitoring of these patients after delivery. The patients will do self-monitored blood glucose (SMBG) using the same memory reflectance meter (glucometer) that they were using during their pregnancy. At the post-partum follow-up visit the data will be analyzed and the patient will be sent for the standard 75 gm oral glucose tolerance test (GTT).

### TECHNICAL APPROACH:

Medical applicataion, status, experimental design, data colection/statistical analysis and further details are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-037

REPORT DATE: 01/29/96

STATUS: Ongoing

TITLE: An Evaluation of the Coagulation Profile in Pregnant Women Treated with Indomethacin for Preterm Labor

START DATE: 01/22/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Higty, Kenneth

ASSOCIATE INVESTIGATOR: Hines

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if pregnant patients treated with indomethacin for preterm labor demonstrate any significant change in their coagulation status.

### TECHNICAL APPROACH:

This will be a cohort study performed on obstetric patients being treated for preterm labor with indomethacin. Patients from both BAMC and WHMC will be eligible for enrollment. Project design, statistics and further details outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-038

REPORT DATE: 01/29/96

STATUS: Ongoing

TITLE: Comparative Assessment of Hypercoagulability in Women With and Without Gynecologic Malignancies Using Thromboelastography

START DATE: 01/22/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Hayes, Edwin

ASSOCIATE INVESTIGATOR: Hines

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To compare the cost, efficacy and side effect profiles of nightly application versus every other night application versus weekly application of Retin-A cream for the treatment of comedonal (blackheads and whiteheads) acne vulgaris.

### TECHNICAL APPROACH:

To evaluate the safety and efficacy of the device. In addition to achieving this objective, the study will supplement the growing body of knowledge concerning the procedure, assisting physicians with some of its technical aspects, aiding them in selecting candidates most likely to benefit from the procedure, and providing them with comprehensive data to use in comparing this form of therapy for coronary artery disease to the presently available alternatives.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-084 REPORT DATE: 06/26/96 STATUS: Ongoing

TITLE: An Evaluation of Antibodies to Human Papillomavirus Types 6, 11, 16 and 18 in Sera and HPV Protein Expression in Tissue of Uninfected and HPV Infected Women: A Pilot Seroepidemiologic Study

START DATE: 06/17/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Hines, Jeffrey

ASSOCIATE INVESTIGATOR: Hall, Bloss, Dixon, Jenson, Ghim

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To serially investigate HPV infection and the antibody response to HPV infection in HPV-infected women and in clinically normal women.

### TECHNICAL APPROACH:

This study will prospectively evaluate the antibody response to HPV infection using an ELISA employing recombinantly synthesized HPV VLPs as antigens. Women who are followed in the routine gynecology, gynecologic oncology, and colposcopy clinics at WHMC and BAMC are eligible for enrollment. Schedule and details outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-085 REPORT DATE: 07/15/96 STATUS: Ongoing

TITLE: Evaluation of the Endometrium in Asymptomatic Postmenopausal Breast Cancer Patients Treated with Tamoxifen: A Comparison of Progesterone Challenge Test Versus Endometrial Biopsy

START DATE: 06/27/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Hines, Jeffrey

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: OB-Gyn FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the ability of the progesterone challenge test to predict abnormal endometrial histology in asymptomatic postmenopausal breast cancer patients on tamoxifen compared to endometrial biopsy.

### TECHNICAL APPROACH:

Asymptomatic postmenopausal women with breast cancer on tamoxifen who are followed in the routine gynecology, gynecologic oncology, and medical oncology clinics at BAMC and WHMC are eligible for participation. Of the 110 patients needed, 80 patients will come from BAMC/WHMC. Specific inclusion criteria and specifics are outlined in protocol.

### PROGRESS:

Annual review is due March 1997.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-105      REPORT DATE: 09/26/96      STATUS: Ongoing  
TITLE: The Effect of Auditory Stimulus on Memory

START DATE: 08/26/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Staten, Patrice L.

ASSOCIATE INVESTIGATOR: Kalk C

DEPARTMENT/SERVICE: OB-Gyn

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if the addition of auditory input will increase the retention of medical information and will lead to higher scores on weekly quizzes and the annual CREOG exam.

### TECHNICAL APPROACH:

Study group will include all current residents in OB/Gyn at BAMC and WHL who are currently PGY1, PGY2 and PGY3. All residents will have access to and be encouraged to utilize a cassette tape learning program designed to expand their memory. All residents will participate in reading their weekly assigned reading and weekly exam.

### PROGRESS:

Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-013 REPORT DATE: 12/01/95 STATUS: Ongoing

TITLE: Islet Cell Hyperplasia of the Pancreas in Adults: An Immunohistochemical and Morphometric Study

START DATE: 04/12/92 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Fish, Melton H.

ASSOCIATE INVESTIGATOR: Enghardt, MH; Smith, JI; Carlin, KJ; Chapa, IA; Ayala, E

DEPARTMENT/SERVICE: Path FACILITY: BAMC

KEY WORDS: Hyperplasia; Pancreas; Immunohistochemical; Morphometric

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine whether or not the pancreatic endocrine volume - measured as area of endocrine tissue and expressed as a percentage of total glandular area - in two BAMC cases of patient with hyperinsulinemic hypoglycemia differs significantly from the relative endocrine volume in pancreata for age - and sex-matched controls. In contradistinction to the studies which disclaim an increase of endocrine volume, we hypothesize that one is present in our cases. It is necessary to address a thorough review of the world's literature in order to completely document experience with diagnosis and with both medical and surgical therapy of hyperinsulinemic hypoglycemia caused by nesidioblastosis/islet cell hyperplasia. Modes of therapy and their outcome from all reported cases in adults, including our own, will be tabulated and evaluated.

### TECHNICAL APPROACH:

Archival tissue from two patients. Control tissues from age and sex matched control pancreata obtained via South Texas Organ Bank. Animal studies not required.

### PROGRESS:

Dec 95: Study is on indefinite hold until purchase of color imaging system by Pathology Dept which probably will not occur until after the move to the new hospital.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-116 REPORT DATE: 07/01/96 STATUS: Ongoing

TITLE: Development of a Synthetic Biologic Control for Immunohistochemical Procedures

START DATE: 08/16/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Enghardt, Michael

ASSOCIATE INVESTIGATOR: Merrill, Gerald; Ayala, Eleanor

DEPARTMENT/SERVICE: Path/Clin Inves FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

Design and manufacture a semisynthetic tissue control using red cell membranes, latex granules and purified antigen.

TECHNICAL APPROACH:

Pig blood will be used as the source of red cells. Blood may be collected from any pig that is on a terminal study and is a part of an approved animal use protocol. The blood will be collected while the animal is anesthetized, just prior to euthanasia. further details in protocol.

PROGRESS:

Jul 96: Basically on "hold" because of the move to the new hospital. No significant progress made (Dr. Enghardt).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-085 REPORT DATE: 02/21/96 STATUS: Completed

TITLE: **Organochlorine Exposure and Breast Cancer**

START DATE: 03/20/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Mego, Thomas S.**

ASSOCIATE INVESTIGATOR: Cassidy, Kohler Sees, Wilson

DEPARTMENT/SERVICE: Pathology FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To measure organochlorine exposure by improved methodology in human breast lipids and blood serum, and determine if there is a relationship to an increased risk for infiltrating ductal carcinoma of the breast.

### TECHNICAL APPROACH:

The hypothesis to be tested is that environmental toxins, specifically the organochlorines oxychlordan, heptachlor epoxide and the DDT residue DDE (dichlorodiphenyl dichloroethane), are associated with infiltrating ductal carcinoma of the breast.

### PROGRESS:

Feb 96: PI was reassigned to Fort Polk. Dr. Enghardt reports that study is completed and he will furnish final data.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-144 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: Surveillance of Antibiotic Resistance Among Invasive Strains of Streptococcus Pneumoniae in San Antonio

START DATE: 10/01/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Whelen, A. Christian

ASSOCIATE INVESTIGATOR: Jorgensen, Patterson

DEPARTMENT/SERVICE: Path

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 21

### OBJECTIVES:

To evaluate CDC's current surveillance system for drug-resistant Streptococcus pneumonia based on the epidemiology of invasive isolates identified at participating sentinel hospitals (most recently 13 hospitals in 12 states. It is proposed to perform active population-based surveillance of invasive pneumococcal infections for a one year period and two period prevalence surveys of adult and pediatric respiratory pneumococcal isolates during the winter months in a large South Texas city to evaluate the sensitivity and representativeness of the current CDC system. This proposal has been prepared in response to and in accordance with CDC RFDP No 200-94-0842(P).

### TECHNICAL APPROACH:

As outlined in protocol.

### PROGRESS:

Sep 96: 21 invasive S. pneumoniae strains have been submitted to Dr. Jorgenson at UTHSCSA for evaluation. Resistance to penicillin is expressed by BAMC isolates more frequently than in other sites in San Antonio. Additionally we seem to have more 3rd generation cephalosporin resistance amongst our penicillin not-susceptible (I or R) isolates. Dr. Dooley has presented some of the information to our therapeutics committee. Population based surveillance is ongoing.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-87-079      REPORT DATE: 02/16/96      STATUS: Completed

TITLE: Appetite and Pectin

START DATE: 09/09/87      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Tiwary, Chandra M.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Pediatrics      FACILITY: BAMC

KEY WORDS: Appetite; obesity

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 74

### OBJECTIVES:

To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

### TECHNICAL APPROACH:

Subjects will be obese children (ages 6-18) attending the pediatric clinic. All subjects will be studied twice at least 3 days apart. Subjects will be given either orange juice or orange juice with pectin. The child will be asked to describe the degree of hunger on a scale of 1 to 20, giving a rating of 1 if most full and 20 if very hungry. The same scale will be used to rate hunger every hour for four hours. At the end of four hours the child will be given ice cream and again asked to rate hunger. Saliva production will be measured on three times - before drinking the juice, 4 hours after drinking the juice, and 1/2 hour after eating the ice cream.

### PROGRESS:

Feb 96: Abstract written and accepted by American College of Nutrition.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-90-062 REPORT DATE: 04/01/96 STATUS: Ongoing

TITLE: High-Dose Chemotherapy with Autologous Bone Marrow Rescue in Children with Recurrent or Progressive Solid Tumors or Primary CNS Malignancies: A Phase II Study (Collaborative Study with Walter Reed Army Med Cen)

START DATE: 05/15/90 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Pick, Terry

ASSOCIATE INVESTIGATOR: Edwards, Glenn; Maybee; David

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC/WRAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To define the toxicities of a regimen of high-dose cyclophosphamide (CY), etoposide (VP-16), and carboplatin (CBDCA) with autologous bone marrow infusion in pediatric patients with recurrent or progressive CNS neoplasms or solid tumors. 2. To measure response rates in a group of patients with refractory solid tumors and CNS malignancies following high-dose chemotherapy and autologous bone marrow infusion.

### TECHNICAL APPROACH:

To be eligible for this study, patients must be < 21 years of age, have an estimated survival of at least 8 wks and have adequate blood counts prior to bone marrow harvest. Therapy will follow the schema outlined in the study protocol.

### PROGRESS:

Apr 96: Continuing; no reportable data as of this date (Dr. Pick).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-002 REPORT DATE: 02/16/96 STATUS: Completed

TITLE: Childhood Obesity: Incidence Density Among Childhood Military Dependents and Association of Obesity with the Duty Status of the Sponsor

START DATE: 01/01/92 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Tiwary, Chandra

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC

KEY WORDS: Childhood Obesity

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 500

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 500

### OBJECTIVES:

To describe the incidence density of childhood obesity among the dependents of US Army personnel. The association between incidence of obesity and the active duty or retiree status of the sponsor will also be assessed.

### TECHNICAL APPROACH:

All children beyond the age of 1 year attending the pediatric and adolescent clinic of the Brooke Army Medical Center will be included in this study. Their order of birth, name, gender, date of birth/age, height, weight, the sponsor's social security number, rank, duty status (active duty or retired), year when retired from the military, age on retirement and the current age will be recorded.

### PROGRESS:

Feb 96: Data needs to be put in computer database for analysis.. Volunteer help is being sought. No adverse affects noted.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-009      REPORT DATE: 01/01/96      STATUS: Terminated  
TITLE: Extracellular Fluid Volume Loading and Prevention of Amphotericin B Nephrotoxicity

START DATE: 10/19/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Gomez, Luisa

ASSOCIATE INVESTIGATOR: Roscelli, John; Cieslak, Theodore; Weise, Martin

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC

KEY WORDS: Extracellular fluid volume; Amphotericin B Nephrotoxicity

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 19

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 19

### OBJECTIVES:

To study the effects of acute extravascular fluid volume expansion at the time of Amphotericin B administration on the prevention of Amphotericin B induced nephrotoxicity in patients less than 23 years of age. The study will be randomized, nonblinded and prospective.

### TECHNICAL APPROACH:

All pediatric patients <23 years of age who require Amphotericin B for suspected or proven deep mycosis will be eligible for the study. Patients excluded from the study will include those with known cardiac disease and those with significant renal disease - specifically a creatinine clearance of <50 ml/min per 1.73 m<sup>2</sup>.

### PROGRESS:

Oct 95: PI PCSd - study terminated.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-061 REPORT DATE: 12/01/95 STATUS: Terminated

TITLE: Low-Volume Blood Culture Sampling in Immunocompromised Children

START DATE: 12/23/92 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Cieslak, Theodore J.

ASSOCIATE INVESTIGATOR: Pick, Terry E.

DEPARTMENT/SERVICE: Pediatrics FACILITY: BAMC

KEY WORDS: Low-volume; High-Volume; Immunocompromised; Children

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

It has previously been suggested that low-volume blood culture sampling is adequate to detect most cases of bacteremia in children. Recent studies, however, demonstrate that large proportion of sepsis in immunocompromised children involves low microbial colony counts. This study will prospectively seek to determine whether high-volume blood sampling for culture will significantly improve the ability to detect bacteremia in this group of children.

### TECHNICAL APPROACH:

Specifics outlined in protocol.

### PROGRESS:

Dec 95: Termination requested. (PI was deployed to Panama.)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-003      REPORT DATE: 01/01/96      STATUS: Terminated

TITLE: Growth and Endocrine Function in Children After Bone Marrow Transplantation

START DATE: 10/19/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Nickels, David A.

ASSOCIATE INVESTIGATOR: Pick, Terry; Potter, Allen

DEPARTMENT/SERVICE: Pediatrics      FACILITY: BAMC

KEY WORDS: pubertal development, endocrine function, BMT

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 16

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 16

### OBJECTIVES:

To prospectively study the effect of BMT on growth, pubertal development, and endocrine function in children undergoing BMT at BAMC.

### TECHNICAL APPROACH:

Study design; data collection/methods; statistical analysis and specifics are included in protocol.

### PROGRESS:

Oct 95: PI PCSd - study terminated.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-006 REPORT DATE: 09/01/96 STATUS: Completed

TITLE: Immunologic Characterization of Coagulase-Negative Staphylococci

START DATE: 08/14/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Cieslak, Theodore J.

ASSOCIATE INVESTIGATOR: Dentler, SM; Battista, MA; Heiman, HS; Fischer, GW

DEPARTMENT/SERVICE: Pediatrics FACILITY: BAMC

KEY WORDS: staphylococci, virulence, commensal strains, serotype

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess the role of coagulase-negative staphylococcal serotype-specificity with respect to virulence. We hypothesize that only serotype II CNS strains are true human pathogens, while commensal strains may be of any serotype. We propose to demonstrate this by comparing commensal and pathogenic strains by means of a simple test of proportions.

### TECHNICAL APPROACH:

Medical applications, status, proposal, methods including statistical analysis and further details are outlined in protocol.

### PROGRESS:

Aug 96: Dr. Cieslak has left BAMC; Dr. Battista reported that study completed as BAMC no longer has neonatal clinic.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-017 REPORT DATE: 12/01/95 STATUS: Terminated

TITLE: **Electrocardiographic Voltage Criteria Are Too Sensitive for Left Ventricular Hypertrophy in Children**

START DATE: 12/13/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Glasow, Patrick**

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Pediatrics FACILITY: BAMC

KEY WORDS: left ventricular hypertrophy (LVH)

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 22

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 22

### OBJECTIVES:

To assess the clinical effectiveness of electrocardiographic (EKG) voltage criteria for detecting left ventricular hypertrophy (LVH), and test efficacy of repeating EKGs prior to proceeding to more expensive tests.

### TECHNICAL APPROACH:

Subject population will be all pediatric patients (age birth - 23, male and female) referred to BAMC pediatric cardiology for possible LVH on EKG (except those with left bundle branch block previously known structural congenital heart disease). The study size will be approximately 100 patients.

### PROGRESS:

Dec 95: PI has PCS'd; termination requested (COL Roscelli).



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-067 REPORT DATE: 02/15/96 STATUS: Terminated

TITLE: Multicenter Double-Blind, Study of Fluconazole in the Early Empirical Treatment of Suspected Fungal Infections in Febrile Neutropenic Patients Undergoing Therapy for Cancer

START DATE: 03/22/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Cieslak, Theodore J.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Pediatrics FACILITY: BAMC

KEY WORDS: Fluconazole, empirical, fungemia, febrile, neutropenic,

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the efficacy and safety of early systemic empiric therapy with fluconazole for the treatment of suspected fungal infections complicating granulocytopenia. (Suspected Fungal Infection is defined as new fever with neutropenia. Proven Fungal Infection is defined as culture and/or biopsy documented invasive fungal infection, esophageal candidiasis, fungemia, or deep visceral fungal infection (e.g., hepatosplenic candidiasis). To determine if fluconazole decreases the need for administra }To determine th

### TECHNICAL APPROACH:

Study design, patient selection, management of study medication and other specifics are outlined in protocol.

### PROGRESS:

Feb 96: This was part of a adult study at Wilford Hall Med Cen wanting to also try in children. WHMC changed their mind. (Never started).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-101 REPORT DATE: 04/01/96 STATUS: Ongoing

TITLE: Effect of Exercise on Blood Glucose Level Among Children with Insulin Dependent Diabetes Mellitus (IDDM)

START DATE: 05/31/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Tiwary, Chandra

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC

KEY WORDS: IDDM

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

To define the effect of exercise on the blood sugar level of the child with IDDM. To find the effect of exercise on plasma and urinary ketones in children with IDDM.

### TECHNICAL APPROACH:

The effect exercise has on the blood glucose level in a child with IDDM may, once defined, be used to prescribe a regular program of physical fitness for the child with IDDM. This knowledge may also be utilized to treat the diabetic child who develops mild hyperglycemia with decreased insulin than might otherwise be required.

### PROGRESS:

Apr 96: No more patients have been enrolled (8 female/2 male), but more are planned. Analysis of results: The blood glucose remains stable or falls after exercise (during treadmill exercise but at home the blood sugar falls consistently after exercise (could be due to less stress at home). The plasma ketone vary after exercise. No adverse effects/no hypoglycemia.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-124      REPORT DATE: 11/27/96      STATUS: Ongoing  
TITLE: **Epidemiologic Study of Cystic Fibrosis**

START DATE: 08/02/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Inscore, Stephen C.**

ASSOCIATE INVESTIGATOR: Schmidt, Joel

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC/WHMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 70

### OBJECTIVES:

1. To longitudinally characterize the variability in and monitor the decline of pulmonary function in CF patients and relate these characteristics to corresponding population factors including age, gender, CF genotype, and organisms infecting the respiratory tract. 2. To longitudinally characterize the rate of pulmonary exacerbations requiring specific antibiotic therapy in CF patients and relate these exacerbations to corresponding population factors including age, gender, CF genotype, and organisms infecting the respiratory tract. 3. To collect info on the safety of long-term treatment with Pulmozyme and to examine trends in pulmonary function and rates of pulmonary exacerbations that relate to the effectiveness of long-term treatment with Pulmozyme.

### TECHNICAL APPROACH:

Inclusion/exclusion criteria, study design, evaluations, and further specifics are outlined in protocol.

### PROGRESS:

Oct 96: Dr. Inscore reports that this is an ongoing multicenter study at Wilford Hall. About 70 patients have been evaluated at Wilford Hall with no adverse effects.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-140 REPORT DATE: 01/01/96 STATUS: Completed

TITLE: A Six Month Randomized, Parallel Group, Double-Blind Clinical Trial Comparing Amloride Hydrochloride with Placebo in Adolescent and Adults with Cystic Fibrosis

START DATE: 08/29/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Inscore, Stephen C.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 6

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 6

### OBJECTIVES:

To compare the efficacy of nebulized amloride hydrochloride 4.5 mg (4.5 ml of 1 mg/ml, QID) with placebo in the treatment of adult and adolescent patients with mild to moderate cystic fibrosis. The primary efficacy assessment will be the decline in pulmonary function over the duration of the trial. Safety assessments will include clinical laboratory tests and collection of adverse events.

### TECHNICAL APPROACH:

Study procedures, data procurement/analysis, clinical supplies, investigator's obligations and specifics are outlined in protocol.

### PROGRESS:

Nov 95: Protocol was completed when last patient enrolled. Results were completed and forwarded to the Primary Investigative Center for analysis and future publications.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-043 REPORT DATE: 02/12/96 STATUS: Terminated

TITLE: Impact of Endotracheal Suctioning with Zero End Expiratory Pressure (ZEEP) versus Positive End expiratory Pressure (PEEP) on Physiology of Premies

START DATE: 03/20/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Sanford, Christine

ASSOCIATE INVESTIGATOR: Chandler, Heiman

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Specific aims of this study are: 1. Is there a difference in oxygenation intracranial pressure, heart rate, transcutaneous carbon dioxide tension, mean airway pressure and blood pressure when premature infants receive endotracheal suctioning using positive end-expiratory pressure versus zero end-expiratory pressure? 2. Is there a difference in the amount of secretions recovered after 3 ETS procedures with PEEP versus 3 ETS procedures with ZEEP in premature infants?

### TECHNICAL APPROACH:

Data analysis, subjects, inclusion criteria and specifics are outlined in protocol.

### PROGRESS:

Feb 96: This study originated at Madigan AMC; BAMC was second site and never funded and thus never started.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-091      REPORT DATE: 02/22/96      STATUS: Completed  
TITLE: **Effect of Storage Method on Urine pH Over Time**

START DATE: 02/06/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **George, Stephen**

ASSOCIATE INVESTIGATOR: Roscelli

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 20

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 20

### OBJECTIVES:

Clean catch urine samples obtained from cooperative Pediatric Ward patients and Pediatric Department staff and house staff will be collected. The pH of specimens stored by several different methods will be measured over set time intervals. Variations in pH by method of storage will be compared to determine if significant differences exist and if so which method best preserves pH.

### TECHNICAL APPROACH:

When evaluating Acid-Base disturbances, and particularly when assessing renal tubular acidosis accurate determination of urine pH is critical for diagnostic and therapeutic reasons. Since immediate measurement of fresh urine is not always achievable, reliable storage methods for preserving urine pH are needed. Further specifics are in protocol.

### PROGRESS:

Feb 96: No adverse affects encountered. It was a worthwhile study and a paper is being processed.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-098 REPORT DATE: 05/01/96 STATUS: Ongoing

TITLE: The Prevalence of Premature Sexual Development in Children Attending the Pediatric Clinics

START DATE: 07/10/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Tiwary, Chandra

ASSOCIATE INVESTIGATOR: Odom, Geralde

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine a) the prevalence of secondary sexual character development among children aged ten years or less who use hormone containing hair preparation b) If the prevalence of premature sexual development between two groups of children, those who use hormone/placenta containing hair preparation and those who do not use such products, is different.

### TECHNICAL APPROACH:

Medical application, status, plan and specifics are outlined in protocol.

### PROGRESS:

May 96: Request for amendment to study has been submitted and is being discussed at this month's meeting.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-135 REPORT DATE: 08/01/96 STATUS: Completed

TITLE: **A Phase III Placebo Controlled Clinical Trial (PC-TNDS-002) to Study the Efficacy of Tobramycin for Inhalation in Patients with Cystic Fibrosis (CF)**

START DATE: 09/11/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Schmidt, H. Joel

ASSOCIATE INVESTIGATOR: Inscore, Westerman

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 5

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 5

### OBJECTIVES:

This study is a multi-center, dbl blind, placebo controlled randomized trial. Patients will receive either aerosolized tobramycin 300 mg twice daily or placebo for 28 days followed by 28 days off study drug. this treatment cycle will be repeated twice for a total of 3 cycles. The projected completion date is 10 months after the initial patient is enrolled..

### TECHNICAL APPROACH:

The overall objectives of this project are to establish the safety and efficacy of twice daily administration of 300 mg tobramycin for inhalation given as repeated, intermittent, short term (28 days) therapy for 168 days in patients with cystic fibrosis who are colonized with *Pseudomonas aeruginosa*. Further details outlined in protocol.

### PROGRESS:

Aug 96: The study was completed 17 May 96 with all 5 patients completing 11 study visits. All of the patients were admitted to the hospital at least once during the study for CF exacerbations unrelated to the study but due to their disease process, four of the five patients have signed consents to continue in the follow-on study pd-T005-004 which is presently ongoing (T-3580).



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-060 REPORT DATE: 09/26/96 STATUS: Ongoing

TITLE: An Open Label Follow On Trial of Tobramycin solution for Inhalation in Patients with Cystic Fibrosis  
(CF) (PC-TNDS-004)

START DATE: 03/21/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Schmidt, H. Joel

ASSOCIATE INVESTIGATOR: Inscore S

DEPARTMENT/SERVICE: Pediatrics

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To further document the safety of twice daily administration of 300 mg tobramycin (5 mL tobramycin solution for inhalation) given as repeated, intermittent, short-term (28 days) therapy in patients with CF who are colonized with *Pseudomonas aeruginosa*.

### TECHNICAL APPROACH:

This study is an open-label trial. Patients will receive 300 mg (5 mL tobramycin solution for inhalation) twice daily for 28 days followed by 28 days off treatment. This treatment cycle will be repeated twice for a total of three cycles over a six-month period.

### PROGRESS:

Annual report due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-016 REPORT DATE: 12/01/95 STATUS: Terminated

TITLE: Comparison of Four Treatment Approaches for Adhesive Capsulitis of the Shoulder

START DATE: 12/14/92 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Deyle, Gail

ASSOCIATE INVESTIGATOR: Bryan, Jean; Halle, John

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC

KEY WORDS: Adhesive Capsulitis; Shoulder

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the efficacy of routine conservative treatments on adhesive capsulitis of the shoulder. Four treatment approaches will be contrasted, with results based on objective measures of passive range of motion and pain assessment as measured with a visual analog scale.

### TECHNICAL APPROACH:

Investigation of the response of shoulders with adhesive capsulitis will be examined over a 24 month treatment period. Effectiveness will be assessed over time and summarized both for the short term response (under six months), and for the long term outcome (from six months to two years). The dependent variables assessed will be passive shoulder range of motion, and pain as assessed with a visual analog scale. Visual analog scales have been validated as ratio scale measures for both chronic and experimental pain. Range of motion will be assessed on the involved shoulder for flexion, extension, abduction, internal and external rotation. Further specifics in protocol.

### PROGRESS:

Dec 95: Collecting data. Anticipate reaching conclusion at end of year.  
(CPT Garber)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-138 REPORT DATE: 11/01/95 STATUS: Terminated

TITLE: Use of An Anti-Spasmotic Medication (Dicyclomine) Prior to Flexible Sigmoidoscopy

START DATE: 11/30/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Cowsar, John D.

ASSOCIATE INVESTIGATOR: Henley, Charles E.

DEPARTMENT/SERVICE: PA Br/AMEDDC&S FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To demonstrate that the pre-administration of dicyclomine prior to flexible sigmoidoscopy can reduce patient discomfort due to bowel spasm during the procedure. The hypothesis is that the anticholinergic, dicyclomine, is significantly more efficacious than placebo in reducing pain during flexible sigmoidoscopy. Another objective of this study is to measure the pressure of air administered through the sigmoidoscopy to insufflate the bowel lumen and attempt to correlate these air pressure measurements with degree of patient discomfort and depth of instrument insertion achieved by the operator.

### TECHNICAL APPROACH:

The hypothesis of this clinical study is that dicyclomine is significantly more efficacious than placebo in reducing discomfort due to bowel spasm, thus allowing a greater depth of scope insertion than placebo during flexible sigmoidoscopy.

### PROGRESS:

Nov 95: Located another study which was essentially same thing. Equipment returned to Dept of Clin Inves.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-107 REPORT DATE: 09/27/96 STATUS: Ongoing

TITLE: **The Comparative Effectiveness of Standard Care, Ultrasound, and Phonophoresis with Fluocinonide Gel for the Treatment of Patellar Tendinitis**

START DATE: 06/23/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Shaffer, Scott**

ASSOCIATE INVESTIGATOR: Randall; Underwood

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC/Reynolds ACH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 40

### OBJECTIVES:

1. Determine if a difference in time to return to duty status exists among subjects treated with ultrasound, ultrasound with 0.05% fluocinonide gel, or standard care. 2. Determine if a difference in visual analog pain scale (VAS) scores exists between subjects treated with ultrasound, ultrasound with 0.05% fluocinonide gel, or standard care. 3. Determine if a difference in distance on a triple hop for distance exists between patients treated with ultrasound, ultrasound with 0.05% fluocinonide gel, or standard care. Etc.

### TECHNICAL APPROACH:

Hypothesis, subject criteria, experimental design and further specifics are outlined in protocol.

### PROGRESS:

Sep 96: Currently analyzing data which looks like about 10-15 more subjects needed. Probably finish 4-6 months. No adverse reactions.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-113 REPORT DATE: 06/01/96 STATUS: Ongoing

TITLE: A Comparison of Two Physical Therapy Treatment Approaches to Shoulder Impingement: Rotator Cuff Exercise Program and Rotator Cuff Exercise with Manual Physical Therapy

START DATE: 07/06/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Deyle, Gail

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Phys Ther FACILITY: BAMC

KEY WORDS: Impingement, rotator cuff

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 29

### OBJECTIVES:

To compare the efficacy of two commonly used physical therapy approaches in the treatment of impingement syndrome of the shoulder.

### TECHNICAL APPROACH:

This study not only provides important information regarding the most effective conservative treatment of this very common physical ailment but also provides a test of the intricate relationship between the cervical spine and shoulder pain.

### PROGRESS:

Jun 96: 29 patients completed at BAMC. 50 total between 3 sites. Data is being analyzed currently. Expected completion of write-up by Oct 96. Presenting results at American Assn of Manual Physical Therapists Annual Conf Nov 96. Expect submission for publication at about that time.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-132      REPORT DATE: 11/29/96      STATUS: Ongoing  
TITLE: Normative Data for the Timed Functional Movements Test

START DATE: 07/26/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Freund, Jane E.

ASSOCIATE INVESTIGATOR: Sargeant, Patricia (Wilford Hall)

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC/WHMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

To determine normative values for Timed Functional Movements in an older adult population. Study design, test description, population, etc are outlined in protocol.

### TECHNICAL APPROACH:

Test description, medications used, and further details outlined in protocol.

### PROGRESS:

Jun 96: Have collected data on 10 subjects without incident. Data collection continues.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-033

REPORT DATE: 12/01/95

STATUS: Ongoing

TITLE: Validation of a Modified Surface Electrode for Sensory Nerve Conduction Testing

START DATE: 12/18/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Underwood, Frank

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC/AMEDDC&S

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

1. Is the peripheral evoked potential in the sural nerve equivalent when recorded using standard electrodes and a modified electrode?
2. Does the use of a modified surface electrode increase the probability of recording a reliable sural nerve response in patients with signs of peripheral neuropathy?

### TECHNICAL APPROACH:

Study design, hypothesis, description of subjects, experimental design and methods are included in the protocol.

### PROGRESS:

Dec 95: Two normal subjects have been enrolled thus far. Some technical problems with the modified electrode are being addressed before more subjects are studied. No adverse reactions.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-102      REPORT DATE: 07/01/96      STATUS: Completed  
TITLE: Effects of Hazardous Chemical Protective Equipment on Static Balance

START DATE: 06/05/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Campbell, Stuart M.  
ASSOCIATE INVESTIGATOR: Hall, Goffar, Elliot

DEPARTMENT/SERVICE: Phys Ther      FACILITY: BAMC/AMEDDC&S  
KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 50  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 50

OBJECTIVES:  
To determine if wear of the Army CPE affects static standing balance using Neurocom's Smart Balance Master for objective measures.

TECHNICAL APPROACH:  
See protocol for details.

PROGRESS:  
Our study showed that the CPE had no significant effect on standing static balance. The study was flawed however with low power due to the small sample size (N=50). However through telephonic contact with Dr. Louis Nashner at Neurocom International it was agreed that if a clinically significant difference had existed we had enough power to detect it.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-103 REPORT DATE: 07/01/96 STATUS: Completed

TITLE: The Effect of Repeated Bouts of Backward Walking at a Constant Workload on Metabolic Efficiency

START DATE: 06/19/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Childs, John D.

ASSOCIATE INVESTIGATOR: Gantt, Higgins, Payne

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC/AMEDDC&S

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 10

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

Rsch Question: Does one become more biomechanically efficient after repeated bouts of backward walking? Study Design: Descriptive statistics will be calculated. VO2 values at the prescribed BW speed will be analyzed with a single-factor repeated measures analysis of variance. Appropriate post-hoc testing will be conducted if the omnibus F ratio is statistically significant (pso.05). The independent variables are status and time, and the dependent variable is VO2 at a fixed workload.

### TECHNICAL APPROACH:

Description of subjects, methods, orientation session, maximal exercise test, and details are included in protocol.

### PROGRESS:

Jul 96: The workload, defined as the BW speed required to elicit a fixed VO2, increased across the 6 week training period, specifically between weeks 4 and 6. Therefore, the prescribed BW speed may need to be increased to maintain a constant energy cost during a BW training period.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-105 REPORT DATE: 05/01/96 STATUS: Completed

TITLE: The effect of back belt use on isometric lifting force and fatigue of lumbar paraspinal muscles

START DATE: 07/20/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Majkowski, Guy R.

ASSOCIATE INVESTIGATOR: Jovag, Taylor, Taylor, Allison, Clayton, Stetts

DEPARTMENT/SERVICE: Phys Ther FACILITY: BAMC/AMEDDC&S

KEY WORDS: Fatigue, Lumbar, Muscle, Isometric contraction, low back pain,

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 32

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 32

### OBJECTIVES:

We will prospectively evaluate all isolated closed small finger metacarpal neck fractures seen at DACH for loss of anatomic position or reduction during immobilization. We will also compare the effectiveness of cast vs. volar splint immobilization and evaluate hand function following treatment of this fracture using immobilization.

### TECHNICAL APPROACH:

All isolated closed small finger metacarpal neck fractures in patients 18 years of age or older seen by the Orthopedic Surgery Service at DACH will be examined (both physically and radiographically) and treated within one week of the initial injury. Each fracture will be evaluated for pain, tenderness, deformity, neurovascular damage, and hand/finger range of motion.

### PROGRESS:

May 96: Notice received that study has been completed.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-107 REPORT DATE: 02/16/96 STATUS: Completed

TITLE: Measures of Balance in Patients Following Total Hip Arthroplasty

START DATE: 08/01/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Newman, David ENS USNR

ASSOCIATE INVESTIGATOR: Dreitzler, Cruse, Stetts

DEPARTMENT/SERVICE: Phys Ther

FACILITY: AMEDDC&S

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 36

### OBJECTIVES:

Research question: (a) Do individuals who have had a total hip arthroplasty and completed a physical therapy rehabilitation program have impaired balance?  
(b) study design: A two-group between-subjects design will be used to assess balance impairment in subjects who have had a total hip arthroplasty (THA) and have completed their post-surgical physical therapy rehabilitation. The dependent variables are the scores on the Berg Balance Scale and the SMART Balance Master Limits of Stability Test; the independent variable will be group status (THA or control).

### TECHNICAL APPROACH:

Null hypothesis, research hypothesis, subjects, methods, statistical design, etc, are outlined in protocol.

### PROGRESS:

Feb 96: As the elderly population continues to grow, there will be a corresponding increase in the number of people undergoing THA. Physical therapists may play an important role in the assessment and treatment of possible balance impairments in this population. We were unable to detect any significant difference in balance ability between individuals who have undergone a THA and a group who didn't have a THA. The research question warrants further inquiry since the statistical power analysis was insufficient to conclude that no difference exists. Future researchers may consider more challenging tests of balance than those used in this study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-040      REPORT DATE: 01/29/96      STATUS: Ongoing

TITLE: Effect of Semi-rigid Lumbosacral Orthosis Use on Oxygen Consumption During Lifting

START DATE: 01/26/96

ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Underwood, Frank B.

ASSOCIATE INVESTIGATOR: Clayton, Roderick

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC/AMEDDC&S

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Rsch questions: Does the use of SRLSO reduce oxygen consumption during a single bout of repetitive lifting, and is there a difference in the effect of the SRLSO based on lifting technique?

### TECHNICAL APPROACH:

The hypothesis, description of subjects, experimental design/methods and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-041

REPORT DATE: 01/29/96

STATUS: Ongoing

TITLE: Effect of Stimulator Position on F-wave latency

START DATE: 01/26/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Underwood, Frank B.

ASSOCIATE INVESTIGATOR: None

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC/AMEDDC&S

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Research question: Does the position of the stimulating cathode and anode affect the latency of the F-wave during clinical electrophysiological testing?

### TECHNICAL APPROACH:

The hypothesis, description of subjects, experimental design/methods and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-042

REPORT DATE: 01/29/96

STATUS: Ongoing

TITLE: Response Stability of Balance Measures Using the NeuroCom Smart Balance Master

START DATE: 01/26/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Wright, David

ASSOCIATE INVESTIGATOR: Cass, Sliter, Kauzlarich

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC/AMEDDC&S

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

Research question: Does repeated testing using computerized dynamic posturography alter measures of balance independently of intervention?

TECHNICAL APPROACH:

The hypothesis, description of subjects, experimental design/methods and further specifics are outlined in protocol.

PROGRESS:

No report available as of this date. Annual review due Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-047      REPORT DATE: 11/01/96      STATUS: Ongoing

TITLE: Prediction of 10-repetition maximum (10-RM) based on hand-held dynamometer force values

START DATE: 02/22/96      ESTIMATED COMPLETION DATE: 02/28/97

PRINCIPAL INVESTIGATOR: Underwood, Frank B.

ASSOCIATE INVESTIGATOR: Allison, Stephen

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC/AMEDDC&S

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 50

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 50

### OBJECTIVES:

Research questions: Can an individual's 10RM be accurately predicted from knowledge of limb length, thigh girth, skinfold thickness, and maximum force production as measured with a hand-held dynamometer?

### TECHNICAL APPROACH:

Hypothesis: This is a regression study, and the null hypothesis is that  $R = 0$ . The primary aim of the study is to develop a regression equation to predict a patient's 10 RM. The predictor variables are those that can be readily measured without inducing fatigue.

### PROGRESS:

Nov 96: Data collection and preliminary analysis completed. No adverse effects.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-048      REPORT DATE: 11/01/96      STATUS: Ongoing  
TITLE: Changes in hip extension range of motion following hip flexor stretching or hip extensor strengthening

START DATE: 02/22/96      ESTIMATED COMPLETION DATE: 02/28/97

PRINCIPAL INVESTIGATOR: Underwood, Frank B.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC/AMEDDC&S

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 28  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 28

OBJECTIVES:

Research questions: Do strengthening exercises of the hip extensor musculature result in greater gains in hip extension than stretching of the hip flexors?

TECHNICAL APPROACH:

Hypothesis: The null hypothesis for this study is that there will be no difference in the length of the hip flexor musculature between groups of subjects who do not change their daily activity, those who stretch their hip flexors, and those who strengthen their hip extensors. The alternative or research hypothesis is that the subjects who strengthen their hip extensors will have greater gains in hip flexor length than the other two groups.

PROGRESS:

Nov 96: Data collection and preliminary analysis complete. No adverse responses.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-049      REPORT DATE: 11/01/96      STATUS: Ongoing

TITLE: **Quadriceps femoris and gluteus maximus activity during stair climbing**

START DATE: 02/22/96      ESTIMATED COMPLETION DATE: 02/28/97

PRINCIPAL INVESTIGATOR: **Underwood, Frank B.**

ASSOCIATE INVESTIGATOR: Allison, Stephen C.

DEPARTMENT/SERVICE: Phys Ther

FACILITY: BAMC/AMEDDC&S

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 30

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 30

### OBJECTIVES:

Research questions: What is the normalized activity of the quadriceps femoris muscle group and the gluteus maximus muscle during stair climbing in asymptomatic individuals?

Study design: Descriptive

Medications used: None.

Subject population: Normal, healthy volunteers.

### TECHNICAL APPROACH:

Hypothesis: This is a descriptive study. The primary aim of the study is to establish the activity of the gluteus maximus and quadriceps femoris muscles during the weight bearing phase of stair climbing in individuals who are free of knee pain.

### PROGRESS:

Nov 96: Data collection and preliminary analysis complete. No adverse responses.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-070 REPORT DATE: 05/23/96 STATUS: Ongoing

TITLE: Training Injuries in Advanced Individual Training: An Exploratory Study

START DATE: 05/13/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Henderson, Nancy E.

ASSOCIATE INVESTIGATOR: Bausch, RS; Poole, M; Chase, C; Shaffer, S; McKenzie, T;  
Mittelstedt, G

DEPARTMENT/SERVICE: Phys Ther FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

By means of a retrospective medical record review, a questionnaire, and monitoring of medical records during advanced individual training (AIT), determine: 1) The percentage of soldiers in AIT who sustained training injuries in basic combat training (BCT). 2) The incidence and type of injuries and reinjuries during BCT and AIT. 3) The percentage of soldiers who sustain injuries in BCT requiring further profiling during AIT; and sustain a recurrence of the injury during AIT. 4) Mechanisms of injury. 5) Epidemiological characteristics associated with training injuries. Provide guidelines for future studies of interventions for injury prevention by identifying the scope of training injuries in an AIT environment.

### TECHNICAL APPROACH:

Medical application, status, subjects, design and methods, data analysis plan and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Mar 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-006

REPORT DATE: 10/01/96

STATUS: Ongoing

TITLE: Psychophysiology of a Neuroleptic 'Therapeutic Window'

START DATE: 11/01/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Orman, David

ASSOCIATE INVESTIGATOR: Rosenstein, Hicks, Clarke, Russell

DEPARTMENT/SERVICE: Psychiatry

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Hypothesis: Moderate doses of haloperidol are associated with a "therapeutic window" characterized by improved negative symptoms, improved sustained attention, increased SPEN saccade number, and elevated startle/evoked potential gating ratios. Specific Aim 1: Determine whether haloperidol induces U- or inverted U-shaped dose-response curves by measuring information processing variables in schizophrenics on stable chronic doses of haloperidol. Aim 2: When chronic doses of haloperidol are modified from low or high levels to a more moderate range (400-800 mg CPZ eqs), improvement of negative symptoms will be proportional to improvements in sustained attention, increased numbers of SPEN saccades, and elevated startle/evoked potential gating ratios. Aim 3, etc, further details listed in protocol.

### TECHNICAL APPROACH:

Specific objectives, medical applications, detailed status, and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-77-012

REPORT DATE: 01/01/96

STATUS: Terminated

TITLE: Intravenous Administration of I131 (NP 59) for Adrenal Evaluation of Imaging

START DATE: 11/15/76

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Sostre, Gilbert

ASSOCIATE INVESTIGATOR: Katz, Neil

DEPARTMENT/SERVICE: Radiology NM

FACILITY: BAMC

KEY WORDS: Adrenal Scan

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 11

### OBJECTIVES:

To evaluate the efficacy and safety of a prolonged post-hospital regimen of enoxparin compared to placebo for the prevention of venous thromboembolic disease in the patients undergoing elective total hip or total knee replacement.

### TECHNICAL APPROACH:

Patient definition and other specifics are outlined in protocol.

### PROGRESS:

Nov 95: As per notification from the FDA and the OTSG, this protocol (IND 12605) has been placed on Inactive status. Protocol was initially intended to make NP-59 readily available for evaluation of adrenocortical abnormalities. Although this product is very useful in this respect, future requests for NP-59 will go through the compassionate IND route. this IND was terminated without prejudice by OTSG.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-89-047      REPORT DATE: 02/01/96      STATUS: Terminated

TITLE: Evaluation of 131I-miBG (131I-meta-iodobenzylguanidine sulfate) in Patients Suspected of Having Pheochromocytoma, Paraganglioma or Medullary Hyperplasia

START DATE: 03/20/89      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Heironimus, James D.

ASSOCIATE INVESTIGATOR: Katz, Neil

DEPARTMENT/SERVICE: Radiology/NM      FACILITY: BAMC

KEY WORDS: Pheochromocytoma; paraganglioma; medullary hyperplasia

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 6

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 40

### OBJECTIVES:

To evaluate the use of 131-I-miBG as an aid in the diagnosis, evaluation, and localization of pheochromocytomas, paraganglioma, neuroblastoma and/or adrenal medullary hyperplasia.

### TECHNICAL APPROACH:

Patients suspected of having pheochromocytoma, paraganglioma or medullary hyperplasia will be eligible. If upon careful consideration of the clinical history, examination and laboratory findings the patient is considered to have reasonable suspicion (>5% possibility) of any of the above conditions, they will be included for study by 131-I-miBG scintigraphy.

### PROGRESS:

Feb 96: I-131 miBG has been approved for use by the FDA. Since the intent of this protocol was to make an IND drug easily available for the above indications, we no longer need this drug under an investigational protocol. Consequently, we request that this study be terminated. No patients have been enrolled within the last year (LTC McBiles, Asst Chief, Nuc Med Svc)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-047      REPORT DATE: 02/08/96      STATUS: Terminated  
TITLE: A Prospective Evaluation of Technetium 99m Sestamibi in The Detection of Breast Cancer

START DATE: 01/01/94      ESTIMATED COMPLETION DATE: / /  
PRINCIPAL INVESTIGATOR: Sostre, Gilberto  
ASSOCIATE INVESTIGATOR: Shah, R; Katz, N; Thomas, J; Sodhi, V; Alvarez, JD  
DEPARTMENT/SERVICE: Radiology      FACILITY: BAMC  
KEY WORDS: Technetium 99m, Sestamibi, validate, establish, sensitivity,  
NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:  
The use of Tc99m Sestamibi in this study would attempt to validate and establish the sensitivity and specificity of Tc99m Sestamibi in detecting breast cancers. This technique would be based on the increased biological differential uptake of breast cancer cells compared to normal breast cells.

TECHNICAL APPROACH:  
It is planned to carry out this open design study in two phases comparing Tc99m Sestamibi uptake in patients who are initially referred for a breast lump to mammography utilizing the abnormal breast biopsy as the gold standard for malignancy. If Tc99m Sestamibi's specificity and sensitivity are proven in discrete, palpable lesions for breast carcinoma malignancy, the second phase would add Tc99mSestamibi scintigraphy to patients undergoing mammography who are found to have diffuse, fibrocystic breast disease or questionable mammograms without palpable lesions who are referred for a diagnostic breast biopsy.

PROGRESS:  
Feb 96: Funding was not approved. The study will not be performed at this time (Dr. Sostre).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-044 REPORT DATE: 12/01/95 STATUS: Ongoing

TITLE: **A Randomized, Double-Blind, Placebo Controlled Study of the Effect of Cilostazol on Gastric Emptying in Patients with Intermittent Claudication Secondary to Peripheral Vascular Disease**

START DATE: 12/19/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Sostre, Gilberto

ASSOCIATE INVESTIGATOR: Williams, Scott

DEPARTMENT/SERVICE: Rad/Nuc Med

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 17

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 17

### OBJECTIVES:

To evaluate the effect of oral cilostazol on gastric emptying in patients with intermittent claudication secondary to peripheral vascular disease. The radionuclide gastric emptying of a standard meal will be performed as a baseline in these patients at entry into the study. On a separate day, the patients will undergo repeat gastric emptying study while on the oral cilostazol for at least 2 weeks. These studies will be compared to the baseline study to determine the effect of cilostazol on the gastric emptying. Further specifics in protocol.

### TECHNICAL APPROACH:

Evaluation of the accuracy and utility of Positron Emission Tomography in the detection and assessment of coronary artery disease.

### PROGRESS:

Dec 95: No adverse effects. Need three more subjects; anticipate completion next month or two.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-089      REPORT DATE: 01/01/96      STATUS: Ongoing  
TITLE: Ureteral Jets in Normal Pregnancy

START DATE: 01/30/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Washowich, Timothy

ASSOCIATE INVESTIGATOR: Burke

DEPARTMENT/SERVICE: Radiology

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 26

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 26

### OBJECTIVES:

To determine the character of ureteral jets as documented by color Doppler in normal pregnant women.

### TECHNICAL APPROACH:

Description of subjects and controls, experimental design and methods, data collection, interpretation and statistical analysis are outlined in protocol.

### PROGRESS:

Jan 96: Data appears to indicate no benefit to evaluating ureteral jets in pregnant women. Data has been collected and is being analyzed. Paper being written. No adverse effects during study.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-002      REPORT DATE: 09/01/96      STATUS: Ongoing

TITLE: **Film-Screen and Direct Digital Mammography: A Comparison of Radiologic Interpretation and Clinical Management Recommendations**

START DATE: 10/05/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Chacko, Anna R.**

ASSOCIATE INVESTIGATOR: Stracener

DEPARTMENT/SERVICE: Radiology      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The objective of this clinical trial is to compare the accuracy of the interpretation of a mammogram obtained by two different techniques, the widely utilized screen-film mammography and direct digital computer-assisted mammography. The study will compare the clinical and management outcomes between these two modalities. The protocol requires that a complete set of mammograms be obtained on each participant utilizing both the film-screen and digital methods. A total of approximately 4000 subjects will participate in the study. The pre-defined endpoint of the analysis in this study is the clinical management outcome and clinical management recommendations by the radiologist after interpretation of the mammogram.

### TECHNICAL APPROACH:

Description of subjects and controls, patient exclusions, experimental design and methods, statistical analysis etc. are outlined in protocol.

### PROGRESS:

Sep 96: Equipment has just been installed; will begin study (Dr. Chacko).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-016

REPORT DATE: 01/05/96

STATUS: Ongoing

TITLE: A Comparison of Power and Conventional Color Doppler Sonography in the Detection of Intratesticular Blood Flow in Prepubertal Males

START DATE: 11/09/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Burke, Brian

ASSOCIATE INVESTIGATOR: Contreras, Dominguez, Dao, Heiman

DEPARTMENT/SERVICE: Rad/Ultra

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

The goal of this prospective clinical trial is to compare power Doppler with conventional color Doppler sonography in the detection of normal intratesticular blood flow in prepubertal males. The Null Hypothesis states that there is no statistical difference between power Doppler and color Doppler in depicting testicular blood flow in this patient population.

TECHNICAL APPROACH:

Descriptions of subjects and controls, experimental design and methods, data collection, statistical analysis and further specifics are outlined in protocol.

PROGRESS:

No report available as of this date. Annual review due Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-021      REPORT DATE: 01/05/96      STATUS: Ongoing

TITLE: Study of Intravenously Administered 111-In Capromab Pendetide in Evaluation of Patients with Prostate Cancer

START DATE: 12/21/95      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: McBiles, Michael  
ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Rad/Nuc Med      FACILITY: BAMC

KEY WORDS:  
NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:  
To further evaluate the utility of immunoscintigraphy using 111 In-capromab pendetide, 0.5 mg in patients scheduled for pelvic lymph node dissection. To further evaluate the utility of immunoscintigraphy using 111 In-capromab pendetide 0.5 mg in patients with suspected residual or recurrent prostate cancer following primary therapy. To further evaluate the safety of intravenously administered 111 In-capromab pendetide in patients with prostate cancer.

TECHNICAL APPROACH:  
It is anticipated that each site will accrue approx 10 to 20 patients and be completed in approx 12 months. Further dosage, selection of patients, supplies, procedure, etc., are outlined in protocol.

PROGRESS:  
No report available as of this date. Annual review due Oct 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-068 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: Digital Mammography: Preliminary Demonstration of Clinical Feasibility

START DATE: 05/09/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Boyle, Edward R.

ASSOCIATE INVESTIGATOR: Glenn, ME; Shaw, RB

DEPARTMENT/SERVICE: Radiology

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Primary aim is to estimate the degree of agreement between film screen mammography and digital mammography in populations of women. Secondary aims: To quantify the variation in degree of agreement between FM and DM according to patient age, overall breast density, breast density in area of lesion; and to examine possible differences in the performance of DM by radiologist reader and facility (groups of readers).

### TECHNICAL APPROACH:

Study design, imaging and interpretation schedule, data collection and statistical analysis and further details outlined in protocol.

### PROGRESS:

Sep 96: Delivery of the SenoScan digital mammography unit which is critical to the protocol was delayed due to it being the first unit installed outside of the Fischer Imaging Corporation. It is now in the process of installation. We hope to begin the project in Sep 96. (Dr. Boyle)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-077 REPORT DATE: 06/11/96 STATUS: Ongoing

TITLE: DoD Screening for Breast Cancer: Where Have All the Women Gone?

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Glenn, Elizabeth

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Radiology FACILITY: BAMC/Air Force in SA

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

BAMC, in conjunction with Air Force medical treatment facilities in San Antonio (Randolph, Kelly, Brooks, Wilford Hall) proposes a unified plan to enhance breast cancer control among DoD eligible female beneficiaries over the age of 35. This proposal will improve screening mammography access with multiple decentralized screening clinics, supported by a central referral facility for multidisciplinary workup and diagnosis of abnormal breast lesions in a streamlined, cost efficient and compassionate environment.

### TECHNICAL APPROACH:

Medical application, status of research, technical approach and other specifics, see protocol.

### PROGRESS:

No report available as of this date. Annual review due Dec 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-097      REPORT DATE: 08/13/96      STATUS: Ongoing

TITLE: Selective Salpingography and Fallopian Tube Recanalization - The Brooke Army Medical Center Experience

START DATE: 07/01/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Trainor, Jr., Philip J.

ASSOCIATE INVESTIGATOR: Stracener

DEPARTMENT/SERVICE: Radiology

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To retrospectively review the nine selective salpingography and fallopian tube recanalization procedures done at BAMC from Feb 94 to Dec 95. The review will evaluate the overall and individual technical success of the procedures, the clinical results of the procedures(s) (i.e., subsequent tubal or uterine pregnancy obtained by the patient), and other issues as they may arise during the process of review.

### TECHNICAL APPROACH:

To establish the efficacy of the procedure at BAMC and to communicate our results with the rest of the medical community within and outside of the Army Medical Department so that others can learn from our experience.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-112      REPORT DATE: 09/01/96      STATUS: Ongoing

TITLE: Simultaneous Transmission/Emission Protocol (STEP) for Attenuation Correction of Breast and Diaphragmatic Attenuation Artifacts During SPECT 99mTc-Sestamibi Myocardial Perfusion Scans in Women Without Coronary Artery Disease

START DATE: 02/01/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: McBiles, Mike

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Rad/Nuc Med

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To quantitatively evaluate the distribution, severity, extent and prevalence of breast, diaphragmatic and soft tissue attenuation artifacts during myocardial perfusion imaging using 99mTc-Sestamibi in women without coronary disease.

### TECHNICAL APPROACH:

This is a pilot study for evaluating the breast and diaphragmatic attenuations in 75 women with 1) bra size of C or greater, 2) 10% over upper limits of lean weight, and 3) less than 5% likelihood of having coronary artery disease. The effect on the variables of breast size and body habitus on apparent perfusion will be analyzed to determine if attenuation correction significantly changes the normal limits in the CEQUAL data base.

### PROGRESS:

Sep 96: 65 volunteers (of the projected 75) with low likelihood of coronary artery disease met criteria for inclusion in the protocol. However, 6 failed the treadmill test, a condition necessary for final inclusion, leaving 59 volunteers with analyzable data. A database has been created for volunteer images and demographic data in a form readable by the PC. This database is in 2 parts, one part contains quantitative data derived from images and the other contains image interpretations from 3 readers. Image manipulation programs have been written to read and display images and header information, read and create structures for data base manipulation. This will allow statistical analysis of the quantitative, image interpreter independent data. Detailed progress statement in file.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-137e REPORT DATE: 09/25/96 STATUS: Ongoing

TITLE: Pediatric Subarachnoid Hemorrhage in Patients with a Cryptic CNS Vascular Malformation, a Case Report and Current Literature Review

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Stoffey, Robert D.

ASSOCIATE INVESTIGATOR: Auber A, Kane A

DEPARTMENT/SERVICE: Radiology

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

A case report detailing the clinical and radiological workup of a fourteen year old white female who presented with subarachnoid hemorrhage, later found to be caused by a left posterior inferior cerebellar artery aneurysm will be presented.

### TECHNICAL APPROACH:

As this study will be mainly an in depth case report and thorough literature review, this topic is not applicable.

### PROGRESS:

This study will not be reviewed until July 1997.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-050 REPORT DATE: 04/01/96 STATUS: Ongoing

TITLE: Comparison of Trigger Point Injections Using Kerolac Tromethamine versus Saline in the Treatment of Myofascial Pain Syndrome

START DATE: 05/02/91 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Schiffer, Dominique

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 14

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 20

### OBJECTIVES:

To determine if kerolac tromethamine is effective in providing pain relief in myofascial pain syndrome, and if so, for how long.

### TECHNICAL APPROACH:

Fifty adult volunteers who are referred to the pain clinic with myofascial pain syndrome will be enrolled in the double blinded, randomized study. Pain intensity and quality will be assessed using pressure algometry visual analog pain scales. Patients will then be given trigger point injection with either ketorolac tromethamine or saline in a double blinded fashion. Pain reassessment will be done at 10 minutes, 6 hours, 1 day and 1 week following injection.

### PROGRESS:

Apr 96: PI reports that numbers have not revealed anything significant as yet; desires to continue study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-073 REPORT DATE: 07/01/96 STATUS: Completed

TITLE: Does Magnesium Decrease the Incidence and Severity of Post-Cardiopulmonary Bypass Arrhythmias: A Double Blind, Randomized, Placebo Controlled Clinical Trial

START DATE: 08/30/91 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mongan, Paul D.

ASSOCIATE INVESTIGATOR: Hays, Janet; Bowman, Greg

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To determine the correlation of mononuclear blood cell (MBC) Mg concentrations with myocardial Mg concentrations. 2. To determine the correlation of myocardial Mg concentrations. 2. To determine the correlation of myocardial and MBC M concentrations with post-CPB arrhythmias (ventricular and supraventricular). 3. To determine if MgSO<sub>4</sub> administration (30 mg/kg followed by 15 mg/kg/hr x 4 hrs) is efficacious in reducing the incidence of post-CPB arrhythmias. 4. To determine the correlation of right atrial and left ventricular myocardial Mg concentration.

### TECHNICAL APPROACH:

Patients will be randomized to receive either 30 mg/kg MgSO<sub>4</sub> or placebo (normal saline) during CPB followed by 15 mg/kg/hr or placebo for 4 hrs. The right atrial appendage (200 mg) will be sampled for intracellular Mg concentration. A left ventricular myocardial sample (200 mg) will be obtained if the left ventricle is to be incised for valve repair or aneurysmectomy. Further details are outlined in protocol.

### PROGRESS:

Jul 96: Dr. Mongan has been reassigned. Dr. Sayson reports that study is completed and report will be forthcoming.

(Dr. Mongan has numbers enrolled, etc./not available here.)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-093 REPORT DATE: 09/01/96 STATUS: Terminated

TITLE: Aeric and Particulate Microemboli as Etiologic Factors in the Development of Neurobehavioral Dysfunction Following Cardiopulmonary Bypass and Vascular Surgery: An Outcome Study

START DATE: 10/07/91 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mongan, Paul D.

ASSOCIATE INVESTIGATOR: Albin, Maurice

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the incidence of air and particulate emboli during cardiopulmonary bypass using transcranial doppler ultrasound as a detection device and to detect, correlate, and follow postoperative neurologic and psychometric changes seen in patients.

### TECHNICAL APPROACH:

This is a multicenter outcome study with UTHSCSA and Wilford Hall Med Cen. 125 patients requiring CPB will be enrolled with 25 patients for peripheral vascular procedures not requiring CPB serving as controls. Psychologic testing and neurologic evaluation will be performed preoperatively, at discharge and at 6 weeks, 6 months and 1 year after discharge. Intraoperative noninvasive testing will consist of transcranial EEG monitoring by a commercially available processed EEG monitor. Anesthetic regimens will be standardized.

### PROGRESS:

Oct 95: We are still awaiting funding by NIH.

Sep 96: Dr. Mongan is now at WRAMC. This protocol should be terminated or removed from consideration (Dr. Sayson).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-026 REPORT DATE: 02/20/96 STATUS: Ongoing

TITLE: **Determination of Vecuronium Bromide Requirements in Nonthermally Injured Patients**

START DATE: 03/17/92 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Mongan, Paul D.**

ASSOCIATE INVESTIGATOR: Thomas, John; Pellegrino, Anthony;

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To determine the ED95 of vecuronium bromide for train-of-four twitch height depression in the nonthermally injured patient. 2. to compare the ED95 determined for these patients to that determined for thermally injured patients.

### TECHNICAL APPROACH:

Patients will be premeditated at the discretion of the anesthesiologist. After placement of monitors and preoxygenation, patients will be induced with sufentanil citrate and thiopental sodium of ketamine as indicated by the patient's condition.

### PROGRESS:

Feb 96: No progress from last year. Finished BAMC portion; awaiting ISR's patient enrollment and data collection before writing paper. No adverse affects.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-068 REPORT DATE: 02/15/96 STATUS: Terminated

TITLE: A Study of Intraincisional Bupivacaine and Intramuscular Ketorolac for Postoperative Pain Relief  
Laparoscopic Bilateral Tubal Electrofulguration

START DATE: 03/25/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Szigeti, Christina

ASSOCIATE INVESTIGATOR: Szigeti, Julius

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS: Bupivacaine;Ketorolac;Electrofulguration

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To compare the post-operative pain relief after operative laparoscopy and bilateral tubal electrofulguration (BTF) using intramuscular (IM) ketorolac alone, ketorolac with intraincisional bupivacaine and intraincisional bupivacaine alone. The total number of patients studied will be 128 (32 in each of the above groups plus a control group who will receive no study drugs). All patients will be American Society of Anesthesiologists (ASA) physical status I or II.

### TECHNICAL APPROACH:

Details including anesthesia, laparoscopic technique, pain evaluation and statistical analysis are outlined in protocol.

### PROGRESS:

Feb 96: Study terminated upon departure of PI. No final report furnished.  
No other Anes physician interested in assuming study. (Dr. Anderson)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-078      REPORT DATE: 03/01/96      STATUS: Ongoing  
TITLE: The Use of EEG and Hemodynamic Parameters in the Design of Intelligent Anesthetic Control Systems

START DATE: 05/14/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Anderson, Douglas M.

ASSOCIATE INVESTIGATOR: Mongan, P;Maghsoudi, R;White, C;Ward, J.

DEPARTMENT/SERVICE: Surg/Anes & Op

FACILITY: BAMC

KEY WORDS: EEG;Hemodynamic Parameters

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This study will collect hemodynamic and physiologic data in conjunction with raw EEG and Auditory evoked Responses from patients undergoing general anesthesia for surgical procedures. This data will be analyzed off-line for correlations of EEG changes with hemodynamic changes that are interpreted clinically as changes in anesthetic depth. Utilizing this information, signal processing techniques, adaptive control theory and artificial intelligence concepts will be applied to develop a anesthesiologist in providing patient care.

### TECHNICAL APPROACH:

This study is descriptive in nature and seeks only to assemble a data base of patient data for future study and analysis.

### PROGRESS:

Mar 96: There has been no progress in this study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-113      REPORT DATE: 07/01/96      STATUS: Completed

TITLE: Effects of Desflurane on the Amplitude and Latency Characteristics of Brainstem Auditory, Midlatency Auditory, Median and Posterior Tibial Nerve Evoked Potent

START DATE: 08/01/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mongan, Paul

ASSOCIATE INVESTIGATOR: Sayson

DEPARTMENT/SERVICE: Surg/Anes & Op      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 6

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 14

### OBJECTIVES:

To determine the effect of desflurane on the amplitude and latency characteristics of multimodality sensory evoked potentials.

### TECHNICAL APPROACH:

Study design, population, methods and specifics covered in protocol.

### PROGRESS:

Jul 96: Dr. Mongan has been reassigned. Dr. Sayson reports that study is completed in that all data has been collected and are currently writing up report. No adverse affects reported.

(Dr. Mongan has details and numbers/not available here.)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-001 REPORT DATE: 09/01/96 STATUS: Completed

TITLE: Magnitude of Hypotension With and Without Intravenous Fluid Preload in Healthy Patients Receiving Subarachnoid Anesthesia

START DATE: 10/01/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Szigeti, Christina

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS: Subarachnoid anesthesiology; hypotension

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 150

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 150

### OBJECTIVES:

To compare the magnitude of hypotension in healthy patients undergoing subarachnoid anesthesia with and without a fluid preload. The total number of patients studied will be one hundred fifty.

### TECHNICAL APPROACH:

It is hypothesized that there will be no difference in the magnitude of blood pressure drop with or without fluid preload in patients receiving SAB. One hundred and fifty patients will be enrolled to obtain statistical significance. Criteria for inclusion and other specifics are outlined in protocol.

### PROGRESS:

Oct 95: Analysis and writing of report pending completion.

Sep 96: Dr. Anderson reports that Dr. Szigeti has left for William Beaumont AMC but study has been completed. No change in patients enrolled.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-005      REPORT DATE: 09/01/96      STATUS: Terminated

TITLE: Oral Atropine Premedication in Children: Effects on Airway and Respiratory Events During General Anesthesia for PE Tube Placement

START DATE: 10/01/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Anderson, Douglas

ASSOCIATE INVESTIGATOR: Richmond, Hunter; Cantees, K; Azarow, K; Redwine, J.

DEPARTMENT/SERVICE: Surg/Anes & Op      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 140

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 140

### OBJECTIVES:

Determine the effect of oral atropine premedication on reducing significant airway and respiratory events during the induction, maintenance, and recovery in children undergoing general anesthesia for PE tube placement.

### TECHNICAL APPROACH:

Study design including hypothesis, statistical analysis and details are included in protocol.

### PROGRESS:

Oct 95: Continuing to evaluate.

Sep 96: Dr. Anderson reports that the original PI Dr. Christopher Swide has left and no one else has pursued study; therefore asks that it be terminated.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-018      REPORT DATE: 12/01/95      STATUS: Ongoing

TITLE: **Determination of Perioperative Intravascular Volume Status in TURP Patients Under Subarachnoid Anesthesia**

START DATE: 12/16/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Storch, Todd D.**

ASSOCIATE INVESTIGATOR: Mongan, PD, Sayson, SC; Anderson; DM

DEPARTMENT/SERVICE: Surg/Anes & Op      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 12

### OBJECTIVES:

To determine and qualify perioperative changes in intravascular volume status secondary to absorption of irrigation solution during TURP. Null hypothesis: No detectable changes in perioperative intravascular volume occur during TURP.

### TECHNICAL APPROACH:

50 ASA 1-3 patients, age 18-90 presenting for elective transurethral procedures under subarachnoid anesthesia will be enrolled. Group A will consist of 25 patients undergoing TURP; group B will be a control group of similar number whose transurethral procedure does not involve prostatic resection. Resection of bladder tumors with irrigation will be deemed acceptable for Group B as substantial absorption of irrigation from bladder tissue has not been demonstrated.

### PROGRESS:

Dec 95: Change in urologic management of benign prostatic hypertrophy stuff to medical management has drastically decreased case load. will continue to enroll available patients; coordination with Urology may become essential. Laser arm of study has been slowed due to decreased acceptance of laser prostatic ablation and stuff to standard TURP or "Vaportrode" method. No preliminary results available 2 - 10 patients in CLAP arm, only 2 in standard TURP arm.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-021      REPORT DATE: 12/01/95      STATUS: Ongoing

TITLE: A Prospective Study Evaluating Optimal Volume of Blood Injected into the Epidural Space for Treatment of Post Dural Puncture Headache

START DATE: 12/21/93      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Sayson, Samuel C.

ASSOCIATE INVESTIGATOR: Shepherd, John M.

DEPARTMENT/SERVICE: Surg/Anes & Op

FACILITY: BAMC

KEY WORDS: Anesthesia, Post dural puncture headache, regional anesthesia,

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 50

### OBJECTIVES:

To assess, in a prospective manner, the optimal volume of blood to be injected into the epidural space for relief of post dural puncture headaches. To compare the effects of using a predetermined volume of epidurally injected blood versus a volume of blood which is titrated to patient tolerance in the relief of PDPH.

### TECHNICAL APPROACH:

Null Hypothesis - There is no difference in failure rate of epidural blood patch for treatment of PDPH when a volume of 5, 10, 15cc of blood is used. Study population, data collection and statistical analysis included in protocol.

### PROGRESS:

Dec 95: Almost at point of reaching point of checking statistics.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-031 REPORT DATE: 01/01/96 STATUS: Terminated

TITLE: Headache After Spinal Anesthesia for Cesarean Section: A Comparison of the Quincke and Whitacre Spinal Needles and the Paramedian and Midline Approaches

START DATE: 01/14/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Szigeti, Christina

ASSOCIATE INVESTIGATOR: Anderson, DM

DEPARTMENT/SERVICE: Surg/Anes & Op

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To compare the incidence of PDPH in pregnant patients receiving spinal anesthesia for cesarean section using two different spinal needles (Quincke and Whitacre) and two different approaches to the subarachnoid space (midline and paramedian). The total number of patients studied will be two hundred (fifty in each group).

### TECHNICAL APPROACH:

Hypothesize: 1. The paramedian approach using the 25 gauge Quincke needle is associated with the same incidence of PDPH as the paramedian approach using the 25 gauge Whitacre needle. 2. The paramedian approach using the Quincke needle is associated with less PDPH than the midline Quincke method. 3. The paramedian approach using the quincke needle is associated with the same incidence of PDPH as the midline Whitacre method. Total number of subjects required for statistical significance is estimated to be 200.

### PROGRESS:

Jan 96: Dr. Szigeti has transferred to William Beaumont AMC. No final report furnished.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-033      REPORT DATE: 01/01/96      STATUS: Completed

TITLE: **The Effect of Transexamic Acid When Given After Cardiopulmonary Bypass and Its Correlation with Thromboelastography**

START DATE: 01/21/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Brown, Robert S.**

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Anes & Op      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 90

### OBJECTIVES:

Will Transexamic Acid (TA) prove to be beneficial after cardiopulmonary bypass routinely or in a subgroup of patients with an abnormal thromboelastography?

### TECHNICAL APPROACH:

Patients will be ASA III-IV patients scheduled for elective nonemergency coronary bypass or valve operation with extracorporeal circulation. All patients will have normal preoperative coagulation profiles and be between the ages of 18 and 80. Exclusion criteria, transfusion criteria and data collection data included in protocol.

### PROGRESS:

Jan 96: Very successful results showing a decrease in bleeding and fewer number of transfusions. Currently writing paper.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-046 REPORT DATE: 02/15/96 STATUS: Terminated

TITLE: A Study of the Ability of Anesthesiologists and Surgeons to Differentiate Arterial from Central Venous Blood Samples by Visual Inspection of Hue

START DATE: 02/08/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Szigeti, Christina

ASSOCIATE INVESTIGATOR: Garman V; Mongan, P

DEPARTMENT/SERVICE: Surg/Anes-Op

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The purpose of this study is to determine whether it is possible for physicians familiar with central line placement are able to differentiate arterial from venous source by visual inspection of the blood in a syringe. The blood will be drawn from arterial lines and internal jugular vein catheters at four different fractional inspired oxygen concentrations to simulate those concentrations most frequently used in the operating rooms. They will be analyzed under low light and bright light conditions by anesthesiologists and surgeons.

### TECHNICAL APPROACH:

This is a descriptive study which will determine the positive predictive value of a visual inspection of hue to determine blood source. Ten patients who require arterial line and central venous catheter placement for their surgery will be enrolled and informed consent will be obtained. After intubation, each patient will be placed on four different F102 (21%, 30%, 50% and 100% for 10 minutes and then 1.5cc sample of arterial and central venous blood will be aspirated into a blood gas syringe. Further details in protocol.

### PROGRESS:

Feb 96: Study terminated upon departure of PI. No final report furnished. No other physician in Anes interested in pursuing study. (Dr. Anderson)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-052      REPORT DATE: 02/20/96      STATUS: Ongoing

TITLE: Incident of Post-dural Puncture Headaches with Continuous Spinal Anesthesia and 24 Gauge Catheter Over 26 Gauge Needle

START DATE: 02/11/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Brown, R. Scott

ASSOCIATE INVESTIGATOR: Becker, Philip J.

DEPARTMENT/SERVICE: Surg/Anes & Op      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To evaluate the incidence of posdural puncture headache (PDPH) with the new Johnson-Bittner 26 gauge needle with which a 24 gauge catheter is passed over the top for continuous spinal anesthesia (CSA) in patients at high risk for PDPH (age 18-40).

### TECHNICAL APPROACH:

It has been proposed that incidences of PDPH with large bore catheters and needles and CSA is 70%. This study will theoretically lower this incidence by using a smaller needle (26 gauge) and tight fitting catheter (24 gauge) to reduce CSF leakage and will avoid complications of cauda equina syndrome by avoiding the use of a microcatheter, 5% lidocaine and any hyperbaric solutions. Patient evaluation, symptoms and specifics are outlined in protocol.

### PROGRESS:

Feb 96: No enrollment yet. Leave open per Dr. Mongan.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-062      REPORT DATE: 02/13/96      STATUS: Completed

TITLE: The Effect of Intravenous Ketorolac on Platelet Function During General Anesthesia

START DATE: 03/10/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thwaites, Brian K.

ASSOCIATE INVESTIGATOR: Nigus, Daren; Bouska, Gregory; Mongan, Paul; Merrill,  
Gerald; Ayala, Eleanor

DEPARTMENT/SERVICE: Surg/Anes & Op      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

To determine whether ketorolac given intravenously has significant effects on platelet function during general anesthesia.

### TECHNICAL APPROACH:

Prior studies demonstrate inhibition of platelet function in awake volunteers in the form of prolonged bleeding times and diminished platelet aggregation studies. Other studies demonstrate that under general anesthesia, platelet function is enhanced and that the production of thromboxane B2 is enhanced. To date, the net effect of general anesthesia and IV ketorolac has not been studied.

### PROGRESS:

Feb 96: Paper has been written on results, due publication. (No further info furnished)



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-073 REPORT DATE: 01/01/96 STATUS: Terminated

TITLE: Sore Throat with the Laryngeal Mask Airway in Pediatric Patients - The Effect of Lubrication

START DATE: 03/25/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Chronister, Tara L.

ASSOCIATE INVESTIGATOR: Sayson, Samuel C; Fontenot, Jason P.

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS: lidocaine

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

To determine if the type of lubrication used on a laryngeal mask airway affects the incidence and severity of sore throat after endotracheal intubation with that of the laryngeal mask. After obtaining informed consent, eligible patients presenting for elective surgery will be randomized into four study groups: 1. Endotracheal intubation; 2. Laryngeal mask airway lubricated with normal saline; 3. Laryngeal mask airway lubricated with KY jelly; 4. Laryngeal mask airway lubricated with 2% lidocaine je

### TECHNICAL APPROACH:

Hypotheses to be tested, technical validity of procedures, sample size, subjects, etc, included in protocol.

### PROGRESS:

Mar 96: Manufacturer now does not recommend the use of lidocaine as planned (Dr. Chronister).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-074 REPORT DATE: 01/01/96 STATUS: Terminated

TITLE: Sore Throat with the Laryngeal Mask Airway - The Effect of Lubrication

START DATE: 04/01/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Chronister, Tara L.

ASSOCIATE INVESTIGATOR: Sayson, Samuel C; Fontenot, Jason P.

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

To determine if the type of lubrication used on a laryngeal mask airway affects the incidence and severity of sore throat after endotracheal intubation with that of the laryngeal mask. After obtaining informed consent, eligibility patients presenting for elective surgery will be randomized into four study groups: 1. Endotracheal intubation; 2. Laryngeal mask airway lubricated with normal saline; 3. Laryngeal mask airway lubricated with KY jelly; 4. Laryngeal mask airway lubricated with 2% lidocaine jelly.

### TECHNICAL APPROACH:

Hypotheses to be tested, technical validity of procedures, sample size, subjects, etc. included in protocol.

### PROGRESS:

Mar 96: Manufacturer now does not recommend the use of lidocaine as planned (Dr. Chronister).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-076 REPORT DATE: 07/01/96 STATUS: Terminated

TITLE: Rocuronium Onset of Action: An EMG dose response study of the adductor pollicis, orbicularis oculi and the adductor muscles of the larynx

START DATE: 02/28/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mongan, Paul

ASSOCIATE INVESTIGATOR: Sayson, Sam; Brown, Scott

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the onset of action and depth of blockade at the adductor pollicis, orbicularis oculi and the muscles of the larynx. To determine the difference in onset of action and depth of blockade with 2X, 3X and 4X an ED95 dose of rocuronium bromide.

### TECHNICAL APPROACH:

Null hypothesis, technical validity of procedures, study design, inclusion/exclusion criteria included in protocol.

### PROGRESS:

Feb 96: No started yet; no enrollment. Leave open per PI.

Jul 96: Due to a PCS to Walter Reed AMC PI requests termination of study. No patients enrolled.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-097 REPORT DATE: 08/01/96 STATUS: Terminated

TITLE: Postoperative Nausea & Vomiting in Females Based on Menstrual History - Effect of Various Prophylactic Antiemetic Regimes

START DATE: 05/10/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Chronister, Tara L.

ASSOCIATE INVESTIGATOR: Pierce

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if three different prophylactic drugs used alone or in combination therapy decrease the incidence of postoperative nausea and vomiting in high risk patients (females of reproductive age undergoing laparoscopic gynecologic surgery). Two hundred and fifty patients will be randomized in 5 groups.

### TECHNICAL APPROACH:

Hypotheses to be tested: Ondansetron, reglan and droperidol used prophylactically alone or in combination decrease the incidence of postoperative nausea and vomiting in females of reproductive age undergoing laparoscopic gynecologic procedures and who are at increased risk based on menstrual history.

### PROGRESS:

Aug 96: Dr. Chronister reports that study should be terminated as it never got off the ground.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-108 REPORT DATE: 05/01/96 STATUS: Ongoing

TITLE: Survey of Current Opinion on the Diagnosis and Treatment of Suspected Intraoperative Malignant Hyperthermia

START DATE: 06/23/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Chronister, Tara L.

ASSOCIATE INVESTIGATOR: Hecker, Richard; Oldroyd, Robert

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To survey anesthesia care providers nationwide to determine current opinion on the diagnosis, management and follow-up care of an intraoperative patient with suspected malignant hyperthermia.

### TECHNICAL APPROACH:

This study is not designed to test a hypothesis. The purpose is to determine the current opinion of anesthesia care providers on malignant hyperthermia treatment issues. Description of subjects, experiment design, data collection and statistical analysis included in protocol.

### PROGRESS:

May 96: Surveys have been returned. Data obtained appears to be inconclusive. Will have others review data before deciding not to report the info.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-115 REPORT DATE: 06/01/96 STATUS: Terminated

TITLE: A Study of Headache After Spinal Anesthesia for Cesarean Section: A Comparison of the Quincke and Whitacre Spinal Needles and the Paramedian and Midline Approaches

START DATE: 07/07/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Swide, Christopher E

ASSOCIATE INVESTIGATOR: Szigeti, Christina; Anderson, Douglas

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC DAH

KEY WORDS: Paramedian, midline, Quincke and Whitacre Spinal needles

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To compare the incidence of PDPH in pregnant patients receiving spinal anesthesia for cesarean section using two different spinal needles (Quincke and Whitacre) and two different approaches to the subarachnoid space (midline and paramedian). The total number of patients studied will be two hundred (fifty in each group).

### TECHNICAL APPROACH:

Hypothesize: 1. The paramedian approach using the 25 gauge Quincke needle is associated with the same incidence of PDPH as the paramedian approach using the 25 gauge Whitacre needle; 2. The paramedian approach using the quincke needle is associated with less PDPH than the midline Quincke method; 3. The paramedian approach using the Quincke needle is associated with the same incidence of PDPH as the midline Whitacre method. Further details outlined in protocol.

### PROGRESS:

Jun 96: Dr. Swide left Darnall Army Hospital and the Army. No one continuing study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-010 REPORT DATE: 01/01/96 STATUS: Completed  
TITLE: A Pilot Study of the Pharmacokinetics and Pharmacodynamics of Etomidate Administered by Inhalation

START DATE: 10/24/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mongan, Paul D.

ASSOCIATE INVESTIGATOR: Anderson, Douglas M.

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 10  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

1. Describe the relationship between plasma etomidate levels and psychometric performance assessment using computer based testing. 2. Determine at what level impairment subjects are aware of dysfunction. 3. Establish a model for testing the effects of anesthetic agents on psychometric performance. 4. Establish the pharmacokinetic and pharmacodynamic effects of etomidate administered by inhalation.

### TECHNICAL APPROACH:

The development of an effective and safe inhalational method for the delivery of anesthetic agents could improve the clinical management of patients.

### PROGRESS:

Nov 95: Completed; data analysis in progress.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-011      REPORT DATE: 12/01/95      STATUS: Completed  
TITLE: Effect of Nebulized Tetracaine on the Hemodynamic Response to Laryngoscopy and Tracheal Intubation

START DATE: 12/28/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Vories, Patricia

ASSOCIATE INVESTIGATOR: Stevens

DEPARTMENT/SERVICE: Surg/Anes & Op

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 30  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 30

### OBJECTIVES:

This study will involve the collection of data relating to changes in hemodynamics during laryngoscopy and tracheal intubation of patients with or without pretreatment with a nebulized local anesthetic. Will be comparing the effect of nebulized tetracaine versus placebo on changes in heart rate and systolic blood pressure in the minutes following laryngoscopy and intubation.

### TECHNICAL APPROACH:

The study will enroll 30 patients of both sexes who are of ASA physical status I or II who are scheduled for elective surgery which will require general anesthesia. Exclusion criteria will include emergency surgery, pregnancy, possible difficult airway, neuromuscular, cardiovascular or intracranial disease. Patients with allergy to local anesthetics will also be excluded.

### PROGRESS:

Dec 95: Study Completed. No adverse effects encountered. Results indicated significant differences in heart rate with lower levels in the tetracaine group compared with placebo at intubation and the subsequent 5 minute intervals. Mean pressure was also significantly less at 1, 3, 4, 5 minutes after intubation. We conclude that tetracaine is well tolerated and may help attenuate hemodynamic response to intubation.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-015 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: A Comparison of Aprotinin and Tranexamic Acid in Reducing Mediastinal Chest Tube Drainage and Allogenic Transfusions After Cardiopulmonary Bypass

START DATE: 01/17/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Mongan, Paul D.

ASSOCIATE INVESTIGATOR: McDonnell, Bryon; Brown, R. Scott; Thwaites, Brian;  
Mongan, Paul

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine whether any difference exists in the ability of Aprotinin and Tranexamic Acid to decrease postoperative blood loss and transfusion therapy after cardiopulmonary bypass.

### TECHNICAL APPROACH:

Tranexamic acid is a primary antifibrinolytic agent that has been shown to decrease mediastinal blood loss and homologous blood transfusion after CPB. Aprotinin is a nonspecific serine protease inhibitor that has also proven to be efficacious in blood conservation in numerous studies, although at a much greater cost than TA. Hence, TA may prove to be as efficacious while conserving costs.

### PROGRESS:

Jan 96: About 80% through with enrollment.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-072      REPORT DATE: 06/19/96      STATUS: Terminated

TITLE: Use of a Priming Dose of Vecuronium Prior to Rocuronium for Rapid Sequence Induction of Anesthesia

START DATE: 04/17/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Stevens, James B.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Anes & Op      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This study will collect data concerning the onset of and recovery from neuromuscular blockade. The investigators hypothesize that the addition of a small "priming" dose of vecuronium will speed onset of neuromuscular blockade when given three minutes prior to administration of a full dose of rocuronium

### TECHNICAL APPROACH:

This study will utilize patients who are ASA physical status I, II, and III and who are scheduled for elective surgery requiring general anesthesia. Exclusion criteria will include: patients with history of neuromuscular, hepatic, renal, or gastroesophageal reflux disease. Patients with abnormal airway anatomy and those taking medications known to interfere with neuromuscular transmission will also be excluded. No pregnant patients will be included in the study.

### PROGRESS:

Mar 96: Dr. Stevens has found that other researchers have done similar comparisons and finds study no longer desirable.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-083      REPORT DATE: 02/12/96      STATUS: Ongoing

TITLE: **Determination of Normal Thromboelastogram (TEG) Parameters in Healthy Pregnant Women at Various Gestational Ages**

START DATE: 02/27/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Chronister, Tara L.

ASSOCIATE INVESTIGATOR: Higby, Singleton, Peters

DEPARTMENT/SERVICE: Surg/Anes & Op      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the "normal" thromboelastogram parameters obtained from healthy pregnant patients at different gestational ages.

### TECHNICAL APPROACH:

Hypotheses, technical validity of procedures, sample size, experimental design and specifics are outlined in protocol.

### PROGRESS:

Mar 96: Number not available but Dr. Higby informs that almost all of the patients have been enrolled.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-092

REPORT DATE: 02/12/96

STATUS: Ongoing

TITLE: **The effect of Epidural Volume on the Spread of Dermatomal Analgesia with Subarachnoid Hyperbaric Bupivacaine**

START DATE: 02/01/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Cheung, Catherine**

ASSOCIATE INVESTIGATOR: **Gridley, Anderson**

DEPARTMENT/SERVICE: **Surg/Anes & Op**

FACILITY: **BAMC**

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 25

### OBJECTIVES:

Determine the effect of epidural injection of different volumes of saline on the extent of sensory anesthesia after administration of subarachnoid hyperbaric bupivacaine.

### TECHNICAL APPROACH:

All patients started on TPN will be invited to participate. The presence of gallbladder sludge and gallstone will be evaluated by standard ultrasound technique. Appropriate images will be obtained for each study to record the findings for later review.

### PROGRESS:

1. To define the toxicities of a regimen of high-dose cyclophosphamide (CY), etoposide (VP-16), and carboplatin (CBDCA) with autologous bone marrow infusion in pediatric patients with recurrent or progressive CNS neoplasms or solid tumors. 2. To measure response rates in a group of patients with refractory solid tumors and CNS malignancies following high-dose chemotherapy and autologous bone marrow infusion.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-119 REPORT DATE: 07/01/96 STATUS: Withdrawn

TITLE: A Direct Comparison of Two Methods for Determining Cardiac Output and Pulmonary Artery Pressure  
in the Operating room: Transesophageal Echocardiography and Pulmonary Artery Catheterization

START DATE: 09/11/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Oldroyd, Robert

ASSOCIATE INVESTIGATOR: Thwaites

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine whether TEE can accurately estimate cardiac output and pulmonary artery pressure in the majority of patients undergoing coronary artery bypass surgery when these estimations are compared to those obtained by PAC.

### TECHNICAL APPROACH:

The hypothesis is that TEE will be able to generate accurate cardiac output and pulmonary artery pressure estimations in a large percentage of patients undergoing cardiac surgery when compared to those values obtained by PAC. Further specifics in protocol.

### PROGRESS:

Jul 96: Dr. Sayson reports that the PI has left BAMC; no one else is interested in pursuing study; therefore study should be withdrawn.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-137      REPORT DATE: 08/01/96      STATUS: Ongoing  
TITLE: Subanesthetic Propofol Infusion for Prophylaxis Against Emesis in Laparoscopic Day Surgery

START DATE: 09/11/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Storch, Todd D.

ASSOCIATE INVESTIGATOR: Duggins

DEPARTMENT/SERVICE: Surg/Anes & Op

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 28

### OBJECTIVES:

To determine if a low dose propofol infusion decreases the incidence of postoperative emetic sequelae after laparoscopic surgery. Null hypothesis: No changes in incidence of postoperative emesis occur after propofol infusion.

### TECHNICAL APPROACH:

Hypothesis to be tested: Low dose propofol infusion is effective in preventing PONV. Desc of patients: Female ASA 1-2 age 18-40 presenting for laparoscopic tubal sterilization procedures. Patients will be assigned to Group A or B by their anesthesia care provider according to a randomization table (blinded to the investigators and PACU personnel).

### PROGRESS:

Aug 96: No complications related to procedure encountered. Data compiled not yet analyzed for statistical significance given early time course in study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-138      REPORT DATE: 09/01/96      STATUS: Ongoing  
TITLE: A Comparison of Prophylactic Ondansetron and Droperidol for strabismus Repair in Adults

START DATE: 10/16/95      ESTIMATED COMPLETION DATE: 06/15/97

PRINCIPAL INVESTIGATOR: Jones, Perry E.

ASSOCIATE INVESTIGATOR: Doe, Brown, O'Hara

DEPARTMENT/SERVICE: Surg/Anes & Op

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 31

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 31

### OBJECTIVES:

To determine whether any difference exists between Ondansetron and Droperidol in the relief of nausea and vomiting in adults undergoing strabismus surgery.

### TECHNICAL APPROACH:

Null hypothesis, sample size, study design, study population, methods, etc., are outlined in protocol.

### PROGRESS:

Sep 96: Study progressing well. Have enrolled 31/100 patients. No significant adverse consequences to date (Dr Jones).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-142      REPORT DATE: 01/05/96      STATUS: Ongoing

TITLE: Hemodynamic Effects of Rocuronium Compared to Vecuronium

START DATE: 07/13/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Stevens, James R.

ASSOCIATE INVESTIGATOR: Hecker, Walker

DEPARTMENT/SERVICE: Surg/Anes

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This study will determine the relative hemodynamic effects of 2-4 x ED95 rocuronium compared to 2 x ED95 vecuronium used during normal maintenance of anesthesia.

### TECHNICAL APPROACH:

To determine the qualitative and quantitative toxicity of Topotecan when given by oral administration over 21 out of every 28 days and to establish an MTD using this schedule. To determine pharmacokinetics and steady state levels achieved after prolonged oral dosing over a range of dose levels and to document any antitumor activity observed using this schedule.

### PROGRESS:

No report available as of this date. Annual review due Mar 97.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-039

REPORT DATE: 01/29/96

STATUS: Ongoing

TITLE: Tracheal Intubation Without Muscle Relaxant: Alfentanil with Thiopental, Propofol, or Etomidate With or Without Lidocaine

START DATE: 01/25/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Stevens, James B.

ASSOCIATE INVESTIGATOR: Anderson, Harris, Walker

DEPARTMENT/SERVICE: Surg/Anes & Op

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the optimal induction agent to use for tracheal intubation without muscle relaxant.

### TECHNICAL APPROACH:

This study will enroll patients who are ASA Physical Status I, and II with Mallampati class I or II airway anatomy and scheduled for elective surgery requiring general anesthesia. Patient selection, risk analysis and specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-093 REPORT DATE: 07/23/96 STATUS: Ongoing

TITLE: **Cisatracurium Neuromuscular Blockade: Speed of Onset Using the Priming Principle and Antagonism with Neostigmine**

START DATE: 07/23/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Stevens, James B.**

ASSOCIATE INVESTIGATOR: Fontenot, Walker

DEPARTMENT/SERVICE: Surg/Anes & Op

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This study will collect evoked data by mechanomyography before and after administration of cisatracurium to determine: 1. Speed of onset of neuromuscular blockade after administration of cisatracurium in divided doses compared to single dose; 2. Speed and completeness of recovery of neuromuscular function after antagonism (reversal) of cisatracurium by various doses of neostigmine.

### TECHNICAL APPROACH:

This study will enroll ASA Physical Status I or II patients who are scheduled for elective surgery requiring general anesthesia. Exclusion criteria will include history of hepatic, renal, or neuromuscular disease. Patients taking drugs that interfere with neuromuscular transmission will be excluded. No pregnant patients will be included in the investigation.

### PROGRESS:

No report available as of this date. Annual review due Feb 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-106e REPORT DATE: 08/19/96 STATUS: Ongoing

TITLE: **Pulse Oximetry Factor Structure in Euvolemic versus Hypovolemic Patients**

START DATE: 08/14/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Walker, Steve**

ASSOCIATE INVESTIGATOR: **Anderson**

DEPARTMENT/SERVICE: **Surg/Anes & Op** FACILITY: **BAMC**

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To identify consistent and salient features of the pulse oximeter wave form via n-dimensional analysis and, 2. To differentiate via plethysmographic pulse oximetry between euvolemic and hypovolemic patients.

### TECHNICAL APPROACH:

This study will utilize patients who are ASA physical status I and II, scheduled for elective surgery and who have been NPO since midnight the night before surgery. Exclusion criteria, etc., included in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-107e      REPORT DATE: 08/19/96      STATUS: Ongoing

TITLE: Aerobic Cultures of Disposable Anesthesia Circuit Systems: A Study of Reuse Safety

START DATE: 08/14/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Walker, Steve

ASSOCIATE INVESTIGATOR: Stevens

DEPARTMENT/SERVICE: Surg/Anes & Op

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if disposable anesthesia circuits remain inoculated with aerobic organisms at the conclusion of anesthesia administration.

### TECHNICAL APPROACH:

This study will enroll patients who are ASA Physical status I and II with Mallampati class I or II airway anatomy, scheduled for elective surgery requiring general anesthesia. Exclusion criteria, etc., outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-110 REPORT DATE: 08/20/96 STATUS: Ongoing

TITLE: Consideration of Cervical Dilation and Parity when Choosing Between Intrathecal and Epidural Analgesia for Labor

START DATE: 08/19/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Smagula, Carl M.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Anes & Op FACILITY: Irwin ACH, Ft Riley

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

To determine at which cervical dilation for primiparous and multiparous women is intrathecal analgesia sufficient to provide analgesia to delivery.

TECHNICAL APPROACH:

120 multiparous and primiparous parturients without significant medical problems, with routine admission lab evaluation at term, requesting analgesia will be recruited. Only patients in active labor with cervical dilation between 3 and 9 cm and with normal fetal heart rate tracings who request analgesia for labor will be considered. Further details in protocol.

PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-048      REPORT DATE: 01/01/95      STATUS: Terminated  
TITLE: Clinical Evaluation of Left Ventricular Assist Device

START DATE: 03/12/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Cohen, David J.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/CT      FACILITY: BAMC

KEY WORDS: Ventricular Assist Device

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

This study is designed to evaluate the use of a Pierce-Donachy Paracorporeal Ventricular Assist Device for patients with one of three problems: 1) post open heart surgery cardiac failure, 2) post myocardial infarction cardiogenic shock, and 3) cardiomyopathy when patients are awaiting heart transplantation and no donor hearts are available. This device is intended for use in patients with heart failure who would otherwise be unable to be supported through conventional medical means. The device would be used for a relatively short period (two to ten days) until either cardiac function returns to a level sufficient to allow for device removal or, in the case of "bridge to transplant," until a donor heart is available. If approval of this project is obtained, we hope to be named an investigational site by the Thoratec Corporation under agreement with the food and Drug Administration.

### TECHNICAL APPROACH:

Specifics are given in protocol.

### PROGRESS:

Apr 96: This protocol has been approved by the FDA. It is no longer under need of investigation and should be cancelled.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-028 REPORT DATE: 01/01/96 STATUS: Terminated

TITLE: Clinical Evaluation of Low Dose Heparin in Conjunction with a Heparin Coated Circuit for  
Cardiopulmonary Bypass

START DATE: 01/11/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Bowman, Greg

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Cardiothor FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To test the safety and efficacy of lower dose heparinization (100 units/kg) in conjunction with a covalently bonded heparin coated (DuraFlow, Edwards Labs) cardiopulmonary bypass circuit in patients undergoing cardiac surgery.

### TECHNICAL APPROACH:

A randomized, prospective analysis of patients undergoing elective coronary artery bypass surgery. Blood samples will be drawn preoperatively, after heparinization but before bypass, at 30 minute intervals during bypass, and 30 minutes after protamine administration. These samples will measure ACT, fibrinopeptide A, platelet count, serum hemoglobin, and fibrinogen. Bleeding time, prothrombin time, partial thromboplastin time, and thrombin time will be measured preoperatively, and 30 minutes and 4 hours after protamine administration.

### PROGRESS:

Has yet to be activated. Pending approval and receipt of funds.

Jan 96: Dr. Cohen reports that COL Bowman retired in 95. Since protocol was never activated, request it be terminated at this time.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-092 REPORT DATE: 01/01/96 STATUS: Terminated

TITLE: Does Preoperative Axillary Ultrasound and Tumor DNA Content Predict Axillary Lymph Node Metastases in Breast Cancer Patients with Clinically Negative Axilla

START DATE: 10/07/91 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Robertson, Frank M.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/SICU

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To prospectively analyze a group of variables to include age, size of primary tumor, receptor status, presence of adenopathy on axillary ultrasound, ploidy status and percent s-phase in breast cancer patients with clinically negative axilla.

### TECHNICAL APPROACH:

Data to include age, primary tumor size, estrogen receptor status, progesterone receptor status, axillary ultrasound, ploidy status, s-phase fraction, and final anatomic pathology results will be collected on all patients treated for breast cancer at BAMC for a period of 18 to 24 months.

### PROGRESS:

Dr Robertson has left and the protocol is on hold. No one on this svc is currently involved in project.

Oct 95: No action since last review, study terminated.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-120      REPORT DATE: 07/01/96      STATUS: Ongoing

TITLE: Menstrual Cycle Impact Upon Breast Cancer - Woman - Surgery Balance

START DATE: 08/01/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Alvarez, Johnny

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Gen Surg      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The prospective observational study described by this protocol will carefully document the menstrual cycle stage of breast cancer or benign breast biopsy and/or breast cancer resection and measure cellular and humoral activities known or suspected to affect metastatic potential in patient samples obtained before and following that biopsy and/or resection.

### TECHNICAL APPROACH:

Study design, treatment plan/flow, clinical evaluation/follow-up, and specifics outlined in protocol.

### PROGRESS:

Jul 96: Study has not been initiated as funds not received. Application is being submitted for another grant .

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-061 REPORT DATE: 02/08/96 STATUS: Ongoing

TITLE: Peritoneal Irrigation in Gunshot Wounds of the Abdomen

START DATE: 03/04/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Kelemen, John J. III

ASSOCIATE INVESTIGATOR: Obney, James; Martin, R. Russell ; Jenkins, Don;  
Kissinger, David

DEPARTMENT/SERVICE: Surg/Gen Surg FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 50

### OBJECTIVES:

To correlate cell count values for peritoneal irrigation with physical examination, peritoneal penetration and the extent of injury in gunshot wounds to the abdomen.

### TECHNICAL APPROACH:

Description of subjects and controls: All individuals brought to BAMC with a gunshot wound to the abdomen. Since the majority of patients with gunshot wounds to the abdomen have a visceral injury, it is estimated that a large number of subjects (200) will be required to generate a non-visceral injury group of sufficient size to attain statistical significance. Experimental design/methods: Exploration celiotomy is currently performed on all patients with gunshot wounds to the abdomen at BAMC. This practice will not be significantly changed or delayed. At the initiation of celiotomy, in stable patients, the abdomen will be lavaged with 1000cc of lactate ringer's solution and a cell count will be performed on the fluid return. The operating surgeons will be blinded from the results of lavage analysis during the operation. Data collection and statistical analysis outlined in protocol.

### PROGRESS:

Feb 96: No adverse affects encountered. Manuscript which discusses the patients enrolled and the progress made to date is available in DCI.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-109 REPORT DATE: 07/01/96 STATUS: Ongoing

TITLE: Biomarkers as Surrogate Endpoints in a Pilot Breast Cancer Chemoprevention Trial Using Tamoxifen

START DATE: 08/02/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Jatoi, Ismail

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Gen Surg FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 2

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 2

### OBJECTIVES:

This study will include over 18 years of age female in- and out-patients. The investigational drug is Tamoxifen supplied by the Univ of Texas. We are entering a new era in breast cancer research in which testing of intentional therapies to prevent the disease will be a major focus. However, little is known about precursor lesions which may herald the eventual development of malignancy. Morphologic assessment identifies premalignant lesions with a higher risk of malignant progression, but this is insensitive.

### TECHNICAL APPROACH:

We hypothesize that certain biological markers which are abnormally expressed in malignant cells may also be abnormal in some premalignant lesions, which might indicate a greater risk of their evolving to cancer. Histological assessment of premalignant lesions an IHC assessment of biomarkers may provide surrogate endpoints for the initial evaluation of new preventive strategies. This project therefore represents a bold and reasonable new step to begin addressing these issues. Details in protocol.

### PROGRESS:

Jul 96: Two patients enrolled with no adverse affects encountered. Want to enroll more patients.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-014 REPORT DATE: 05/01/96 STATUS: Withdrawn

TITLE: A Randomized, Dbl-Blind, Multicenter Trial Assessing the Safety and Efficacy of a Single Intravenous Dose of CP-116,517 Compared with Cefotetan for the Prophylaxis of Infection Following Elective Colo-rectal Surgery

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Fengler, Scott A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Gen Surg

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To evaluate the efficacy of CP-116,517 when given as a single intravenous dose compared with a single intravenous dose of cefotetan in the prophylaxis of infection following elective colo-rectal surgery. To compare the safety and toleration of a single intravenous dose of CP-116,517 to a single-dose regimen of cefotetan.

### TECHNICAL APPROACH:

Study population, treatments and specific details outlined in protocol.

### PROGRESS:

May 96: Informed by FACT that Pfizer and National Medical Research Corporation have cancelled study at this site. National enrollment goals have been met, and there is no longer the need for additional patients.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-061 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: General Surgery Selective Management of Stable Patients with Suspected Tangential Gunshot Wounds to the Abdomen

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Kelemen, John J.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Gen Surg FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To evaluate the effect of selective management of stable patients with suspected tangential gunshot wounds to the abdomen using diagnostic peritoneal lavage on the non-therapeutic celiotomy rate and morbidity.

### TECHNICAL APPROACH:

Description of subjects and controls: All individuals brought to BAMC with suspected tangential gunshot wound to the abdomen and a systolic blood pressure of at least 90 mmHg on arrival. Experimental design/methods, data collection and further specifics are outlined in protocol.

### PROGRESS:

To be reviewed Apr 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-073

REPORT DATE: 05/28/96

STATUS: Ongoing

TITLE: Bone Marrow Micrometastases in Premenopausal Breast Cancer: Relevance to Timing of Surgery

START DATE: 05/20/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Jatoi, Ismail

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Gen Surg

FACILITY: BAMC /Univ of

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

It is hypothesized that there is an increased risk of bone marrow micrometastases during the follicular phase when compared to the luteal phase of the menstrual cycle in patients with early stage primary breast cancer; also that surgery promotes the growth of these occult metastatic cells.

### TECHNICAL APPROACH:

Premenopausal women with early stage breast cancer will be enrolled into the study at the time of diagnosis. The institutions participating in the study will include hospitals affiliated with The Univ of Cincinnati, those affiliated with the Northern New Jersey Cancer Association, and hospitals associated with the UCLA School of Medicine. Statistics/feasibility, methods and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Nov 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-88-079      REPORT DATE: 08/01/96      STATUS: Ongoing  
TITLE: Collaborative Ocular Melanoma Study (COMS)

START DATE: 08/08/88      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Holck, David  
ASSOCIATE INVESTIGATOR: Van Hewen (UTHSCSA)

DEPARTMENT/SERVICE: Surg/Oph      FACILITY: BAMC/UTHSCSA/WHMC  
KEY WORDS: Melanoma

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 4

### OBJECTIVES:

To determine the efficacy of enucleation versus plaque irradiation in the treatment of medium size ocular melanomas. To determine the efficacy of enucleation without pre-operative external radiation versus enucleation combined with pre-operative external radiation in the treatment of large ocular melanomas. To determine the clinical course and community treatment standards in the treatment of small ocular melanomas.

### TECHNICAL APPROACH:

Unchanged. Collaborative Ocular Melanoma Study is designed to determine the most effective way to treat choroidal melanomas. Patients are divided into small tumors, medium tumors and large tumors based on diameter and thickness of the melanoma. Individuals in the small category are observed while individuals in the medium category are randomly divided into two treatment groups. One group was enucleated and the second will have radiation plaque therapy applied to the melanoma.

### PROGRESS:

Aug 96: No patients enrolled. After counseling, no patients have elected to go with study. Original PI Dr. Slade has PCSd to Korea (Dr. Stuart Farris). David Holck (670-6815; WHMC) has assumed PI duties and reports 2 patients at Wilford Hall and 2 at UTHSCSA.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-041 REPORT DATE: 05/01/96 STATUS: Completed

TITLE: Efficacy and Safety of Ciprofloxacin Ophthalmic Ointment Vs TOBREX Ophthalmic Ointment for Treating Bacterial Conjunctivitis in Children

START DATE: 06/28/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: O'Hara, Mary

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Oph FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The objectives of this study are to compare clinical and bacterial efficacies and incidence of adverse reactions for topical Ciprofloxacin Ophthalmic Ointment against TOBREX in children (ages 2-12) with acute bacterial conjunctivities. Acute is defined as having a duration of one week or less.

### TECHNICAL APPROACH:

Materials/methods, subjects, study procedure, statistical evaluation, etc., furnished in protocol.

### PROGRESS:

May 96: Study completed. No patients were ever enrolled. Study was completed by another institution before BAMC was able to register a patient.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-018 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: Intraocular Silicone Oil in Surgery for Otherwise Inoperable Retinal Detachment

START DATE: 01/23/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Bauman, Wendall C.

ASSOCIATE INVESTIGATOR: Dunlap, Weldon

DEPARTMENT/SERVICE: Surg/Oph

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if silicone oil will be effective in the treatment of retinal detachment and restoring vision in eyes in which the retina cannot be reattached by conventional methods and the vision would otherwise be permanently decreased. The safety of silicone oil and its side effects are also to be evaluated.

### TECHNICAL APPROACH:

Subject selection, study design and procedures to be performed, managing adverse reaction, etc, are outlined in protocol.

### PROGRESS:

Oct 95: This trial has not yet begun accrual as drug availability was a problem. A supply has now been delivered and it is anticipated that accrual will begin the last week of Oct 95.

Jan 96: This has just opened due to prior problems with drug availability.

Dec 96:

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-116 REPORT DATE: 07/01/96 STATUS: Ongoing

TITLE: Intraocular Pressure Response to Nasal Steroids

START DATE: 08/09/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Campagna, John A.

ASSOCIATE INVESTIGATOR: Chacko, Ortiz, Hayes, Doe

DEPARTMENT/SERVICE: Surg/Ophthal

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 10

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 10

### OBJECTIVES:

a. To determine the intraocular pressure (IOP) response to nasal steroids. b. To determine if there are any risk factors for the development of an increased IOP with nasal steroids, i.e., diabetes mellitus, myopia, or family history of glaucoma.

### TECHNICAL APPROACH:

Prospective, controlled, randomized, single blinded study comparing IOP response in patients on nasal steroids (Beclomethasone) vs IOP response in patients receiving a nonsteroidal agent (Cromolyn sodium) for the treatment of allergic rhinitis. k Sample size will be 116 patients.

### PROGRESS:

Jul 96: No adverse effects noted. Low enrollment is due to few interested patients from referring clinics (ENT, Allergy). Will attempt to increase enrollment via discussions with staff of each service (ENT, Allergy).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-133      REPORT DATE: 08/01/96      STATUS: Completed

TITLE: A Research Study to determine the Effect of Punctal Occlusion on Intraocular Pressure in Patients  
Taking Topical Glaucoma Therapy

START DATE: 09/08/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Leuschner, Edward F.

ASSOCIATE INVESTIGATOR: Chako

DEPARTMENT/SERVICE: Surg/Oph

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 8

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 8

### OBJECTIVES:

To determine if with complete punctal occlusion and with the glaucoma medication contained in the tear lake for a longer period of time, there is a clinically measurable and beneficial result: the lowering of intraocular pressure.

### TECHNICAL APPROACH:

Intend to prove whether or not the clinical outcome of successful therapy for glaucoma is affected by punctal occlusion with silicone plugs. The test patients will have bilateral glaucoma and dry eye. The patients will be on monotherapy with a beta blocker. The alternative hypothesis is that there will be a decrease in the IOP in the treated eye.

### PROGRESS:

Aug 96: PI has PCS'd but senior paper written on study. Results: Punctal occlusion was not shown to be of therapeutic benefit. there was a clinically significant decrease in the intraocular pressure of both eyes during the control phase of the study, but this proved not to be of statistical significance with a study population of this size.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-003      REPORT DATE: 08/01/96      STATUS: Ongoing

TITLE: A Prospective, Randomized Clinical Trial Comparing Topical Prednisolone 1% to Diclofenac 0.1% in the Treatment of Pseudophakic Cystoid Macular Edema (PCME)

START DATE: 09/29/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Bauman, Wendall C.

ASSOCIATE INVESTIGATOR: Barnes, Scott

DEPARTMENT/SERVICE: Surg/Oph

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

To objectively assess the efficacy of topical diclofenac as a treatment modality for post-cataract cystoid macular edema (PCME). To compare prednisolone and diclofenac as treatment for PCME. To assess the safety of long term (potentially up to four months) use of topical diclofenac.

### TECHNICAL APPROACH:

Inclusion, exclusion criteria, methods, statistical analysis, etc, are outlined in protocol.

### PROGRESS:

Aug 96: No adverse affects reported.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-029 REPORT DATE: 05/01/96 STATUS: Completed

TITLE: A Prospective Multicenter Non-Randomized Clinical Study to Evaluate Viteron as an Intraoperative Surgical Aid in the Giant Retinal Tear Patients

START DATE: 12/20/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Dunlap, Weldon A.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Oph FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The study group will include approximately 50 study subject and 50 controls.. This study will compare post-tonsillectomy (1) pain, (2) tolerance of diet, i.e., liquids vs soft vs regular, (3) swelling, (4) temperature (5) weight fluctuation and (6) complications between patients receiving dexamethasone or placebo perioperatively.

### TECHNICAL APPROACH:

Indication for use, contraindications, study design, safety and effectiveness parameters and further criteria are outlined in protocol.

### PROGRESS:

May 96: Closed by company. Study has reached patient accrual. Ready to get FDA marketing approval.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-135 REPORT DATE: 10/01/96 STATUS: Ongoing

TITLE: **Determination of Prevalence of Clinical and Subclinical Keratoconus in Patients with Mitral Valve Prolapse**

START DATE: 09/23/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Chacko, Benjamin**

ASSOCIATE INVESTIGATOR: Alabata, Doe, Welford, Ferguson

DEPARTMENT/SERVICE: Surg/Oph FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To perform a case control study to determine the association of keratoconus in patients with echocardiographic evidence of mitral valve prolapse. Keratoconus is a non-inflammatory ocular condition in which there is apical thinning and protrusion of the cornea. Previous studies have demonstrated an association between keratoconus and mitral valve prolapse.

### TECHNICAL APPROACH:

Study will compare the prevalence of clinical and subclinical keratoconus in patients with and without mitral valve prolapse. This study is also unique in that it will use newer and more sensitive diagnostic tests such as corneal topography to establish the association between keratoconus and mitral valve prolapse. Corneal topography is available at the new BAMC Oph Clinic. Early detection of keratoconus may aid in earlier therapeutic intervention for this disease.

### PROGRESS:

Due annual review Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-035      REPORT DATE: 02/20/96      STATUS: Completed

TITLE: Use of a Foot Compression Pump in the Prevention of Deep Vein Thrombosis in Hip Fractures

START DATE: 02/25/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Stannard, James P.

ASSOCIATE INVESTIGATOR: Harris, Robert M; Allgood, Brian D; Bucknell, Allan

DEPARTMENT/SERVICE: Surg/Ortho      FACILITY: BAMC

KEY WORDS: DVT, Foot Pump; Deep Vein Thrombosis; Hip Fractures

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 29

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 40

### OBJECTIVES:

To determine the clinical usefulness of the AVI foot pump as prophylaxis for deep venous thrombosis associated with hip fractures in individuals greater than 40.

### TECHNICAL APPROACH:

All male and female patients greater than 40 years of age sustaining a femoral neck fracture of intertrochanteric fracture presenting to the BAMC Orthopaedic Surgery Service within 48 hours of injury and requiring operative intervention without a history of prior deep venous thrombosis, without concomitant lower extremity precluding the use of a foot pump, not on warfare in therapy for other medical problems and not pregnant will be eligible for inclusion in the study.

### PROGRESS:

Feb 96: Dr. Stannard will obtain and furnish detailed specifics . No adverse affects encountered.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-009      REPORT DATE: 01/01/96      STATUS: Terminated  
TITLE: **The Incidence of Concomitant Leg and Foot Compartment Syndrome**

START DATE:      /      /      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: **Dahl, James A.**

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Orthopedic      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the incidence of foot compartment syndrome concurrent with leg compartment syndrome.

### TECHNICAL APPROACH:

The patients would be drawn from the population treated at BAMC and would consist of any patients presenting for evaluation and treatment of tibial fractures or suspected acute leg compartment syndrome. Specifics are given in protocol.

### PROGRESS:

Haven't had anyone eligible during year.

Nov 95: Terminate study; PI PCSd and no one else interested in pursuing.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-081 REPORT DATE: 01/01/95 STATUS: Completed

TITLE: Mechanical Characteristics of the Femoral Intramedullary Nailing Systems Available from Five Different Manufacturers

START DATE: 04/07/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Wilkey, Keith D.

ASSOCIATE INVESTIGATOR: Mehserle, William

DEPARTMENT/SERVICE: Surg/OrthoSurg FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the mechanical characteristics of five commonly used femoral intramedullary nails. We will examine, in vitro, the stiffness (rigidity), strength, and fatigue characteristics of the entire device, including the majority of the proximal and distal ends. A range of values regarding the strength, stiffness, and fatigue strength will be obtained. Superior and inferior designs will be identified.

### TECHNICAL APPROACH:

Literature review summary, medical application, materials/methods, etc., outlined in protocol.

### PROGRESS:

Mar 96: Study has been completed (results forthcoming). (Dr. Wilkey)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-011 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: Vascular and Gross Anatomy of the Patellar Tendon

START DATE: 10/30/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Wahlgren, Van

ASSOCIATE INVESTIGATOR: Stanton

DEPARTMENT/SERVICE: Surg/Ortho

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To specifically define the vascular supply and the gross anatomy of the patellar tendon through radiographic studies and anatomical dissections.

### TECHNICAL APPROACH:

This will be a descriptive study of the vascular and gross anatomy of the patellar tendon. An MRI will be conducted to look at the vasculature of a "normal" patellar tendon. We will also seek arteriograms with appropriate run-off views to demonstrate the vasculature. Finally, a cadaveric dissection will be made to define the size, shape, fiber orientation and attachments of the patellar tendon; as well as the contributions of the quadriceps tendon, various bursae and the patellar fat pad to the patellar tendon anatomy.

### PROGRESS:

No report available as of this date. Annual review due Sep 96.  
Sep 96: Tendons have been dissected and measured. Mounting is to be requested. Study delayed by several months due to TDY of study investigators.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-015

REPORT DATE: 01/05/96

STATUS: Ongoing

TITLE: Flexor Tendon Repair: The Analysis of the Bulk of Repair Measured as Resistance to Gliding

START DATE: 12/08/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Komas, Nicholas

ASSOCIATE INVESTIGATOR: Deffer, Jones, Bucknell

DEPARTMENT/SERVICE: Surg/Ortho

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To establish a model to measure and compare the resistance of gliding of three flexor tendon repair methods. To test these same three methods of tendon repair for ultimate tensile strength.

### TECHNICAL APPROACH:

1. To determine the long-term safety and efficacy of doxazosin tablets in hypertensive patients with benign prostatic hyperplasia. 2. To obtain information regarding the optimal dose of doxazosin tablets required on a long-term basis for patients with BPH.

### PROGRESS:

No report available as of this date. Annual review due Dec 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-035      REPORT DATE: 01/29/96      STATUS: Ongoing  
TITLE: Use of Intermittent Plantar Compression to Treat Swelling Associated with Calcaneal Fractures

START DATE: 01/15/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Stannard, James P.

ASSOCIATE INVESTIGATOR: Bucknell; Harris & Early (UTSWMC Dallas)

DEPARTMENT/SERVICE: Surg/Ortho

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To prospectively evaluate the results of a pneumatic foot pump in the preoperative reduction of swelling of the soft tissues associated with calcaneal fractures.

### TECHNICAL APPROACH:

All patients with intraarticular calcaneal fractures will be advised of this study if they meet the inclusion and exclusion criteria. Inclusion criteria are: age 18-50 years, unilateral intraarticular calcaneal fractures, English or Spanish speaking, patient able to personally consent (no head injuries), and surgery able to be performed within 14 days of the fracture. Exclusion criteria and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-046

REPORT DATE: 02/22/96

STATUS: Ongoing

TITLE: A Comparative Trial of 2-Octyl Cyanoacrylate for the Approximation of Incised or Lacerated Skin

START DATE: 02/07/96

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Stannard, James

ASSOCIATE INVESTIGATOR: Wahlgren, Van

DEPARTMENT/SERVICE: Surg/Ortho

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The overall objectives of this study are (1) to evaluate the clinical performance, in terms of safety and effectiveness, of TraumaSeal when used in the approximation of incised or lacerated skin; (2) to compare the performance of this device to commercially available skin closure devices, specifically, adhesive wound closures (i.e., strip type adhesives), nonabsorbable sutures, or staples; and (3) to substantiate the advantages this device may have over the commercially available skin closure devices.

### TECHNICAL APPROACH:

The hypothesis, study population, design, and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Nov 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-054 REPORT DATE: 09/02/96 STATUS: Ongoing

TITLE: Comparison of Three vs Four Cortical Fixation of the Injured Distal Tibiofibular Syndesmosis in Cadavers

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Baumann, Richard L.

ASSOCIATE INVESTIGATOR: Soldatis, Ward

DEPARTMENT/SERVICE: Surg/Ortho

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Construct a cadaveric model in order to compare two methods of distal tibiofibular syndesmosis fixation. Surgically destabilized ankles will be stabilized with three versus four cortical syndesmosis screws in order to assess range of motion, security of fixation, and cycles to failure. Appropriate security of fixation, and cycles to failure. Appropriate treatment recommendations will be made based on the outcome.

### TECHNICAL APPROACH:

Study will aid the orthopaedic surgeon in making treatment decisions in patients with unstable ankle injuries. Hypothesis, design and methods, and further specifics are outlined in protocol.

### PROGRESS:

No report as of this date. Annual review due in Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-076 REPORT DATE: 07/01/96 STATUS: Ongoing

TITLE: Efficacy of Steroids in Reducing Post-Tonsillectomy Morbidity

START DATE: 08/30/91 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Esquivel, Carlos

ASSOCIATE INVESTIGATOR: Ramirez, Sylvester G.

DEPARTMENT/SERVICE: Surg/Oto

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 40

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 105

### OBJECTIVES:

To determine whether the use of intravenous perioperative steroids (dexamethasone) enhances the overall recovery in patients undergoing tonsillectomy: (1) by reducing postoperative pain, (2) by reducing postoperative swelling, and/or (3) allowing improved oral intake.

### TECHNICAL APPROACH:

The study group will include approximately 50 study subject and 50 controls. This study will compare post-tonsillectomy 1) pain, 2) tolerance of diet, i.e., liquids vs soft vs regular, 3) swelling, 4) temperature 5) weight fluctuation and 6) complications between patients receiving dexamethasone or placebo perioperatively.

### PROGRESS:

Jul 96: Dr. Carlos Esquivel reports that he is taking over as PI replacing Dr. James Lee. Dr. Esquivel reports that there have been no adverse affects encountered and study is ongoing.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-032      REPORT DATE: 01/01/96      STATUS: Terminated  
TITLE: Evaluation of Gastroesophageal Reflux in Preterm Infants

START DATE: 01/01/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Otto, Russell J.

ASSOCIATE INVESTIGATOR: Gastroesophagel Reflux; Preterm infants

DEPARTMENT/SERVICE: Surg/Oto      FACILITY: BAMC

KEY WORDS: Gastroesophgeal Reflux; Preterm Infants

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine whether gastroesophageal reflux can be reliably evaluated in intubated premature neonates. Sequential cases will be considered for inclusion in the study. The study population will consist of mechanically ventilated infants approximately 25-36 weeks gestational age.

### TECHNICAL APPROACH:

Study plan, design, population, conduct of the study plan, and further specifics are outlined in protocol.

### PROGRESS:

95: PI has PCSd from BAMC and protocol has not been assigned to another PI. Study remains ongoing.

Jan 96: Dr. David Malis reports study is terminated as no one is currently interested in pursuing study.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-051 REPORT DATE: 02/09/96 STATUS: Ongoing

TITLE: Mandibular Reconstruction by Distraction Osteogenesis

START DATE: 03/23/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Ramirez, Sylvester G.

ASSOCIATE INVESTIGATOR: Costantino, Peter D., WHAFMC

DEPARTMENT/SERVICE: Surg/Oto FACILITY: BAMC/WHAFMC

KEY WORDS: Mandibular Reconstruction; Distraction Osteogenesis

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. Reconstruct segmental mandibular defects in selected human subjects by applying distraction osteogenesis; and 2. critically evaluate the efficacy of distraction osteogenesis for mandibula reconstruction in humans as compared to standard techniques.

### TECHNICAL APPROACH:

Methods, significance, risk/benefit ratio, and other specifics outlined in protocol.

### PROGRESS:

Feb 96: To date no patients have been entered at BAMC. No costs have been incurred. Study remains ongoing for patient accrual.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-045      REPORT DATE: 02/09/96      STATUS: Ongoing

TITLE: The M-40A1 Protective Masks' Effect on Sleep: A Preliminary Study

START DATE: 02/27/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Ramirez, Sylvester G.

ASSOCIATE INVESTIGATOR: Vories, Andrew

DEPARTMENT/SERVICE: Surg/Oto

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To conduct a preliminary study to observe physiologic changes resulting from the use of M-40A1 Protective Mask (PM) during sleep. The purpose of the proposed study is to examine the physiologic consequences of using the PM during sleep, specifically we expect changes in sleep onset, time spent in Rapid Eye Movement (REM) sleep, oxygen levels, hypopneas, and apneas.

### TECHNICAL APPROACH:

Subjects, exclusion criteria , materials/apparatus and specifics are outlined in protocol.

### PROGRESS:

Feb 96: The coordination with the Sleep Lab and Student Company, BAMC, has been completed. Awaiting receipt of funds from MRMS.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-068 REPORT DATE: 02/08/96 STATUS: Ongoing

TITLE: The Effect of a Peridex Rinsing Regimen on Wound Infection Rates in Major Head and Neck Surgery

START DATE: 02/27/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Balbuena, Luis

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Oto FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 3

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 3

### OBJECTIVES:

To conduct a double blind randomized clinical trial to determine the effect of a perioperative oral rinsing regimen with chlorhexidene (Peridex) on the wound infection rate in major head and neck surgery.

### TECHNICAL APPROACH:

Hypothesis: Perioperative oral rinses w/Peridex will decrease the bacterial count of human saliva thereby decreasing the bacterial inoculum causing wound infections in patients undergoing major head and neck surgery.

Materials/methods, statistical analysis, etc, are outlined in protocol.

### PROGRESS:

Feb 96: The study is ongoing. There has been a decrease in the number of patients undergoing major head and neck surgery, hence fewer than anticipated participants. No adverse affects have been encountered.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-070      REPORT DATE: 01/01/96      STATUS: Completed

TITLE: **Racial Variations in Cephalometric Analysis**

START DATE: 01/30/95

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Lee, James J.**

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Oto

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 89

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 120

### OBJECTIVES:

To evaluate racial variations of mean values in cephalometric analysis. Specifically, one value will be investigated, PAS. this will be accomplished by comparing PAS value in six different groups: Caucasian males, Caucasian females, Black males, Black females, Hispanic males and Hispanic females.

### TECHNICAL APPROACH:

The hypothesis is that in cephalometric analysis, Posterior Airway Space do differ with racial and gender background.

### PROGRESS:

Jan 96: Project has been completed, has recently been submitted to the American College of Surgeons for publication.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-90-091 REPORT DATE: 01/01/96 STATUS: Completed

TITLE: Phase I Protocol for the Evaluation of Active Immunization Against LHRH in Patients with Metastatic Cancer of the Prostate

START DATE: 10/07/91 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thompson, Ian M.

ASSOCIATE INVESTIGATOR: Randin, Peter M.; Mueller, Edward J.; Zeidman, Eric  
J.; Desmond, Paul

DEPARTMENT/SERVICE: Surg/Urol FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 4

### OBJECTIVES:

1. To determine whether active immunization with a luteinizing hormone releasing hormone based vaccine will result in a significant immune response to LHRH in patients with metastatic prostatic cancer. 2. To determine if immunization against LHRH will cause suppression of luteinizing hormone and follicle stimulating hormone (FSH) levels in these patients. 3. To observe patients for signs of adverse effects following immunization.

### TECHNICAL APPROACH:

Four patients from BAMC will be referred on the study. The LHRH vaccine will be administered by Dr. Ravdin at the UTHSCSA on three occasions at two week intervals. Patients will return to BAMC for follow-up at monthly intervals for the first six months and then every three months for up to 2 yrs.

### PROGRESS:

Oct 95: This study is now closed - effective 28 Aug 95. We have not been impressed with the hormonal effect in hormonally naive patients and have therefore opted to close the study.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-91-074 REPORT DATE: 08/01/96 STATUS: Ongoing

TITLE: **Randomized Prospective Study Comparing Radical Prostatectomy Alone versus Radical Prostatectomy Preceded by Androgen Blockade in Clinical B2 Prostate Cancer**

START DATE: 09/14/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Thompson, Ian M.**

ASSOCIATE INVESTIGATOR: Rozanski; Foley; Schow , Renfer

DEPARTMENT/SERVICE: Surg/Urol

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 8

### OBJECTIVES:

To evaluate the safety and efficacy of a combination of Lupron Depot 7.5 mg (leuprolide acetate for depot suspension) and Eulexin (flutamide) prior to radical prostatectomy in clinical stage B2 prostatic cancer as compared to no therapy before radical prostatectomy.

### TECHNICAL APPROACH:

Eight patients with clinical stage B2 carcinoma of the prostate were randomized to receive either radical prostatectomy or adjuvant hormonal therapy. Patients eligible for the study must have had no evidence of extraprostatic disease.

### PROGRESS:

Aug 96: Study enrollment is complete. The five patients remaining on study are seen every 6 months and monitored for disease progression or recurrence. During this reporting period, no patients were dropped from the study for disease progression. Five patients continue to return for follow-up.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-057      REPORT DATE: 07/01/96      STATUS: Ongoing

TITLE: Prostatic Intraepithelial Neoplasia as a Predictor of Subsequent Development of Carcinoma of the Prostate

START DATE: 04/14/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thompson, Ian M.

ASSOCIATE INVESTIGATOR: Cho, Moo; Brawer, Michael (Univ of WA Health Sci Cen

DEPARTMENT/SERVICE: Surg/Urol      FACILITY: BAMC

KEY WORDS: Prostatic; Neoplasia; Carcinoma; Prostate

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the association of PIN and AAH with subsequent development of CAP in men with benign prostatic hyperplasia (BPH).

### TECHNICAL APPROACH:

The slides of the pathologic evaluation of the benign glands in the 333 men who underwent TURP for BPH between 1980 and 1983 will be recovered. The slides will then be forwarded to Dr. Michael Brawer at the Univ of Washington for evaluation. The evaluation will be made in a "blinded" manner - i.e., the physician will not be aware of which patients subsequently developed carcinoma of the prostate.

### PROGRESS:

This study still has yet to be activated. We are currently awaiting support from the VA Cooperative Trials group for pathologic processing.

4/95: Status remains unchanged.

Aug 96: No change in study status (Dr. Thompson).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-023 REPORT DATE: 01/01/96 STATUS: Ongoing

TITLE: Phase III Trial of Coumarin (1,2-Benzopyrone) in Patients with Clinically Localized Prostatic Carcinoma Treated by Radical Prostatectomy Found Pathologically to Have High Risk of Recurrence

START DATE: 01/01/92 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thompson, Ian M.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Urol FACILITY: BAMC

KEY WORDS: Coumarin;Prostatic Carcinoma;Prostatectomy

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

1. Determine whether coumarin therapy prevents progression or delays time to progression compared to placebo. 2. Evaluate the qualitative and quantitative toxicities of coumarin administered for prolonged periods.

### TECHNICAL APPROACH:

The coumarin therapy including drug information details, eligibility criteria, descriptive factors, pretreatment evaluation and treatment plan are outlined in protocol

### PROGRESS:

Jan 96: Accrual has been closed. Current patient is stable without side effects of Rx.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-078      REPORT DATE: 02/22/96      STATUS: Ongoing

TITLE: Survival and Morbidity Tradeoffs in Prostate Cancer Treatment - Impact of Patient Perspective

START DATE: 02/28/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thompson, Ian M.

ASSOCIATE INVESTIGATOR: Johnson, Jean; Helfrick, Barbi; Schow, Douglas; Renfer, Leonard; Rozanski, Thomas; Ward, J

DEPARTMENT/SERVICE: Surg/Urol      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 330

### OBJECTIVES:

To compare men with different prostate cancer conditions on their choice of treatment, factors which influence treatment choices, and perceptions about treatment risks and benefits. To examine the relationship between the maximum acceptable risk for the minimal acceptable benefit of treatment. To identify the best predictors of treatment choice. To examine the relationship between decision style and treatment choice.

### TECHNICAL APPROACH:

A descriptive study will be done to compare five groups of men with different prostate cancer conditions in regard to their decision for treatment when survival and morbidity tradeoffs are considered. Specific subject groups, data collection methods, instruments, data analysis, etc., included in protocol.

### PROGRESS:

Feb 96: It is anticipated that the first interim analysis will be conducted after enrolling 400 patients. Very interesting information about patient tradeoffs is appearing in the data. No adverse events.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-093      REPORT DATE: 04/01/96      STATUS: Terminated

TITLE: A Phase II Study: Intravesical N-Trifluoroacetyl Adriamycin-14-Valerate (AD 32) in Patients with Cell Carcinoma in situ of the Bladder Who Have Failed or Have Recurrence Following Treatment with Bacillus Calmette-Guerin

START DATE: 05/09/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thompson, Ian M.

ASSOCIATE INVESTIGATOR: Renfer, Leonard; Pollard, Cathy; Helfrick, Barbi

DEPARTMENT/SERVICE: Surg/Urol

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess the efficacy of intravesical instillations of AD 32 and to evaluate the quantitative toxicities associated with it.

### TECHNICAL APPROACH:

After determining by physical exam and microscopic examination of the urine that the patient does not have a urinary tract infection, 4 vials of the study drug are diluted and infused into the patient's bladder, using aseptic technique. The patient is instructed to hold the medication for at least 2 hours. This procedure is repeated at weekly intervals x 6.

### PROGRESS:

To compare the activity of two doses (25 and 50 mcg/kg/d) of recombinant human interleukin 11 (NEUMEGA rhIL-11 Growth Factor) with a placebo in ameliorating severe chemotherapy-induced thrombocytopenia in cancer patients receiving a variety of chemotherapy regimens and to gain additional information regarding the safety of rhIL-11 administration at the specified doses. Also to assess whether IL-11 antibodies are produced and to measure IL-11 serum levels.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-094      REPORT DATE: 04/01/96      STATUS: Terminated

TITLE: A Phase II Study: Intravesical N-Trifluoroacetyladiamycin-14-valerate (AD 32) in Patients with Transitional Cell Carcinoma of the Bladder

START DATE: 05/09/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thompson, Ian M.

ASSOCIATE INVESTIGATOR: Renfer, Leonard; Pollard, Cathy; Helfrick, Barbi

DEPARTMENT/SERVICE: Surg/Urol

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To assess the efficacy of intravesical instillations of AD 32, to evaluate the qualitative and quantitative toxicities associated with it and to evaluate qualitative information on efficacy and toxicity associated with 6 installations versus 9.

### TECHNICAL APPROACH:

After determining by physical exam and microscopic examination of the urine that the patient does not have a urinary tract infection, 4 vials of the study drug are diluted and infused into the patient's bladder, using aseptic technique. The patient is instructed to hold the medication for at least 2 hours. This procedure is repeated at weekly intervals x 6 in half the patients and x 9 in half the patients.

### PROGRESS:

Design, eligibility, treatment plan, adverse experiences, statistical analysis, etc, outlined in protocol.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-133      REPORT DATE: 07/01/96      STATUS: Withdrawn  
TITLE: Effects of Breast Cancer on Prostate Cancer Risk

START DATE: 08/15/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Cornum, Rhonda

ASSOCIATE INVESTIGATOR: Thompson, Ian M; Scanlon, Clare

DEPARTMENT/SERVICE: Surg/Urol

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine if the risk of prostate cancer in men with first degree (mother, daughter, or sister) female relatives with breast cancer is different from men with no first degree relatives who have breast cancer. This is an epidemiologic study. Test subjects will be first degree relatives of women who have been diagnosed with breast cancer at BAMC over the past twenty years; the control population will be first degree relatives of women who had breast biopsies but in whom no cancer was found.

### TECHNICAL APPROACH:

Nov 95: No further patients were enrolled since the last reporting period. A total of only 4 patients were enrolled, which was inadequate to provide any meaningful data. Patients were difficult to recruit and the PI has PCSd to Madigan AMC. No other physicians willing to take over study.

### PROGRESS:

Jul 96: Dr. Cornum reports that survey is not turning out to be worthwhile. It seems the patients being surveyed are not able to correctly respond to questions, therefore data is not useable. She states that furtunately no costs were involved in this study and asks that it be withdrawn.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-012      REPORT DATE: 01/19/96      STATUS: Ongoing

TITLE: Use of Alpha-Adrenergic Blocking Agents Compared to Anti-Cholinergic Agents and Placebo in Women with Obstructive/Irritative Voiding Symptoms

START DATE: 12/05/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thompson, Ian

ASSOCIATE INVESTIGATOR: Friedrichs, Paul; Cespedes, Duane; Helfrick, Barbi;  
Johnson, Jean; Martin, Scott

DEPARTMENT/SERVICE: Surg/Urol      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

As outlined in the protocol.

### TECHNICAL APPROACH:

To compare the efficacies of oral cimetidine and diphenhydramine alone and in combination for the treatment of acute urticaria.

### PROGRESS:

Annual review due Dec 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-082      REPORT DATE: 08/01/96      STATUS: Ongoing  
TITLE: A Clinical Trial of Medical Therapy in Benign Prostatic Hyperplasia

START DATE: 12/19/94      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Foley, John P.**

ASSOCIATE INVESTIGATOR: Thompson; Dobbs; Rozanski; Schow

DEPARTMENT/SERVICE: Surg/Urol

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 47  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 47

### OBJECTIVES:

The primary objective of the NIH-BPH clinical trial is to ascertain if medical therapy (finasteride and/or doxazosin) delays or prevents the progression of BPH. The primary outcome will be the time to clinical progression of BPH. Participants will be classified into one of four categories (outlined in protocol).

### TECHNICAL APPROACH:

Study design, eligibility criteria and detailed specifics are outlined in protocol.

### PROGRESS:

Feb 96: Dr. John P. Foley will replace Dr. Ian M. Thompson as PI on this protocol. No further info furnished.

Sep 96: All patients enrolled are compliant and returning for appropriate follow-up. Two serious adverse events were reported (on the same patient) which were also sent to the FDA. Nine non-serious adverse events have been reported to the IRB.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-087      REPORT DATE: 03/01/96      STATUS: Completed  
TITLE: Sampling Error in Posttherapy Prostate Biopsy

START DATE: 03/06/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thompson, Ian M.

ASSOCIATE INVESTIGATOR: Rozanski, Renfer, Schow, Cho, Greenspan

DEPARTMENT/SERVICE: Surg/Urology      FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 56

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 56

### OBJECTIVES:

Determine the rate of false-negative sextant biopsy in patients with biopsy-proven prostate cancer.

### TECHNICAL APPROACH:

100 consecutive patients who undergo radical prostatectomy will be studied. After the prostates are removed to be forwarded to the department of Pathology, sextant biopsy of the prostate will be performed. Both the radical prostatectomy specimen and the prostate gland will thereafter be forwarded for pathologic processing.

### PROGRESS:

Mar 96: This study is complete. Fifty-six patients studied. False negative biopsies in 45%. If they received hormone therapy preoperatively, false rate was 61%. Did not go to 100 patients as significant rate achieved of 56.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-123      REPORT DATE: 07/01/96      STATUS: Ongoing

TITLE: Comparative Study of the Clinical Efficacy of Two Dosing Regimens of EULEXIN

START DATE: 08/14/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Rozanski, Thomas

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Urol

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 1

### OBJECTIVES:

To examine an alternative method for sedating patients while the ophthalmologist is anesthetizing the eye. this method of sedation has been studied in a smaller number of patients in another project. This project will be done on approximately 116 patients.

### TECHNICAL APPROACH:

Multi-center, open label, prospective randomization. Further specifics are in protocol.

### PROGRESS:

Study design/method, specific aim, background and significance and further details are included in protocol.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-140 REPORT DATE: 06/01/96 STATUS: Ongoing

TITLE: Results of Transurethral Incision/Resection of the Prostate in Men Treated Medically for Benign Prostatic Hyperplasia

START DATE: 10/12/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Schow, Douglas

ASSOCIATE INVESTIGATOR: Thompson, Rozanski

DEPARTMENT/SERVICE: Surg/Urol

FACILITY: BAMC

### KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine the degree of improvement following surgical therapy for BPH in men receiving medical therapy for symptoms of prostatism. To characterize those men who elect surgical therapy following medical therapy for prostatism.

### TECHNICAL APPROACH:

Medical applications, inclusion/exclusion criteria, sample size and further details are covered in protocol.

### PROGRESS:

Jun 96: With Dr. Schow on TDY, this study has not yet opened for patient accrual. Hope to open Sep 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-001      REPORT DATE: 09/01/96      STATUS: Ongoing  
TITLE: Creation of a Prostate Cancer Data Base

START DATE: 10/01/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Foley, John P.

ASSOCIATE INVESTIGATOR: Higgins

DEPARTMENT/SERVICE: Surg/Urol

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To retrospectively collect data on prostate cancer (CaP) patients during the period 1980 to present. 2. To prospectively collect data on patients with prostate cancer. 3. To develop and maintain an accurate, reliable, secure database on patients with CaP. 4. To coordinate similar data collection at other military hospitals and medical centers in order to create a Dept of Defense prostate cancer database.

### TECHNICAL APPROACH:

The CPDR database will allow us to record, organize and analyze the wealth of information we have regarding our daily experiences detecting and treating prostate cancer. Status, Plan and further details are outlined in protocol.

### PROGRESS:

Sep 96: MS Higgins reports that the doctors are starting to register patients, numbers not available. Awaiting funds from WRAMC.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-002      REPORT DATE: 10/04/96      STATUS: Ongoing  
TITLE: Pilot Study: Linkage Analysis of Prostate Cancer Families

START DATE: 10/03/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Thompson, Ian M.

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Urol      FACILITY: BAMC/UTHSCSA

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To ascertain multigeneration families with multiple members having prostate cancer at an age 65 or less years, and to evaluate whether this sample is appropriate and powerful enough for finding disease susceptibility genes with genetic linkage analysis.

### TECHNICAL APPROACH:

Specific aims: 1. Determine whether the clustering of prostate cancer in the sample of multiplex families is consistent with mendelian inheritance of a susceptibility gene. 2. Assess the power of the sample for discovering susceptibility genes for prostate cancer using genetic linkage analysis.

### PROGRESS:

Annual review due Sep 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-017 REPORT DATE: 01/05/96 STATUS: Ongoing

TITLE: Center for Prostate Disease Research (CPDR) Prostate Cancer Radical Prostatectomy Follow-Up Questionnaire

START DATE: 12/14/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Friedrichs, Paul

ASSOCIATE INVESTIGATOR: Rozanski, Schow, Foley, Clark, Waguespack, Cornum

DEPARTMENT/SERVICE: Surg/Urol

FACILITY: BAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

To test the validity of a three-element nonlinear model for estimating aortic flow waveform morphology in man.

### TECHNICAL APPROACH:

Subjects for this study will be recruited from the tumor registry of all RP patients treated at BAMC between 1980-1995. A personal computer-based database has been created to enter and tabulate survey data. Most of the results will be descriptive statistics of morbidity percentages. The statistical procedures will be performed using the Statistical Analysis System (SAS) computer package.

### PROGRESS:

No report available as of this date. Annual review due Dec 96.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-094      REPORT DATE: 07/31/96      STATUS: Ongoing

TITLE: A Phase II Study to Determine the Effect of Finasteride & Flutamide on Patients with Rising PSA's Who have had Radical Prostatectomy, Radiation, or Cryoablation Treatment for Localized, Primary Prostate Cancer

START DATE: 07/30/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: MacIsaac, Stephen G.

ASSOCIATE INVESTIGATOR: Mataban

DEPARTMENT/SERVICE: Surg/Urol

FACILITY: Evans ACH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine in patients with Stage A, B, C or D1 cancer of the prostate: 1. The likelihood of response in order to assess whether daily finasteride and daily flutamide should be advanced to other studies; mainly, a Phase III randomized trial and, 2. Toxicity of daily finasteride combined with daily flutamide, and 3. Likelihood of potency to be maintained in patients who were potent before the study.

### TECHNICAL APPROACH:

Drug information, eligibility criteria , treatment plan and further details are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Mar 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: REPORT DATE: 07/15/96 STATUS: Pending

TITLE: Spouse Abuse Among Active Duty Women Married to Civilian Husbands: An Examination of Interpersonal and Social Factors

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Newborn, Jesse

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Social Work

FACILITY: BAMC/WRAMC etc

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

Specific: To identify military-unique stressors or circumstances which may contribute to the development of an abusive relationship among AD women; and to determine if there is a higher prevalence of certain interpersonal relationship patterns among active duty women and civilian men in an abusive situation.

General: To elucidate possible risk-factors for domestic violence in the US Army population; and to collect information which would facilitate development of more effective spouse abuse prevention programs in the US Army population.

### TECHNICAL APPROACH:

General: To elucidate possible risk-factors for domestic violence in the US Army population; and to collect information which would facilitate development of more effective spouse abuse prevention programs in the US Army population.

### PROGRESS:

No report available as of this date. Annual review due May 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-92-007 REPORT DATE: 02/01/96 STATUS: Terminated

TITLE: Comparison of Cimetidine, Ranitidine, and Diphenhydramine in the Treatment of Acute Urticaria Over a Seventy-two hour Period.

START DATE: 02/01/92 ESTIMATED COMPLETION DATE: 02/01/94

PRINCIPAL INVESTIGATOR: Ferrara, Anthony

ASSOCIATE INVESTIGATOR: Moscati, Ronald M.

DEPARTMENT/SERVICE: Emer Med

FACILITY: DAH

KEY WORDS: Acute urticaria;cimetidine;ranitidine;diphenhydramine

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 4

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 18

### OBJECTIVES:

To determine the effectiveness of cimetidine, ranitidine and diphenhydramine in the treatment of acute urticaria during the immediate ER follow-up period.

### TECHNICAL APPROACH:

Subjects in this study will include 130 male and female patients between the ages of 16 and 55 presenting to the Emergency Room at Darnall Army Community Hospital with signs and symptoms consistent with acute urticaria of less than 24 hr duration. Presenting symptoms should include itching, swelling, and rash.

### PROGRESS:

Feb 96: PI graduated two years ago. No one else assumed duties and no further data available (Dr. Coppola).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-002      REPORT DATE: 01/01/96      STATUS: Terminated

TITLE: Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas

START DATE: 10/01/92      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Wroblewski, Carl S.

ASSOCIATE INVESTIGATOR: Kadakia, Shailesh

DEPARTMENT/SERVICE: Med/Gastro      FACILITY: DAH

KEY WORDS: Aspirin; NSAID; Distal Colonic Neoplasms

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To determine whether a statistically significant difference exists in the prevalence of distal colonic adenomas by fiberoptic flexible sigmoidoscopy of distal colonic adenomas by fiberoptic flexible sigmoidoscopy (FSS) in a population of aspirin or NSAID users and nonusers.

### TECHNICAL APPROACH:

Eligible patients will have a FFS performed by physicians in either the Internal Medicine or Gastroenterology Clinics after proper counselling. A colon cleansing preparation consisting of two Fleets one hour prior to the examination will be administered.

### PROGRESS:

Oct 95: Analysis pending and will be incorporated into the BAMC site data.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-93-128      REPORT DATE: 05/01/95      STATUS: Completed

TITLE: **A Prospective Randomized Double-Blinded Evaluation of Prochlorperazine versus Sumatriptan for the ED Treatment of Migraine Headache**

START DATE: 08/16/93      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **Hammond, Kevin**

ASSOCIATE INVESTIGATOR: Cline, David; Coppola, Marco; Karnes, Margaret; Yealy, Donald

DEPARTMENT/SERVICE: Emerg Med      FACILITY: DAH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 70

### OBJECTIVES:

Description of subjects/experimental design, data collection and detailed specifics are outlined in protocol.

### TECHNICAL APPROACH:

Patients between the ages of 18 and 60 who present to our Emerg Depts with a migraine headache as defined by the Ad Hoc Committee on classification of Headache will be entered into the study. Exclusions and further specifics are outlined in the protocol.

### PROGRESS:

Jul 96: Dr. Coppola reports that study completed in May 95. Abstract w/results have been published.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-040 REPORT DATE: 01/01/96 STATUS: Terminated

TITLE: Efficacy and Safety of Ciprofloxacin Ophthalmic Ointment Vs TOBREX Ophthalmic Ointment for Treating Bacterial Conjunctivitis in Children

START DATE: 01/28/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Foster, Mark S.

ASSOCIATE INVESTIGATOR: McDonnold, JT; Moore, RH; Foster, MS

DEPARTMENT/SERVICE: Surg/Oph - DAH FACILITY: Darnall/BAMC

KEY WORDS: Ciprofloxacin, TOBREX, conjunctivitis

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The objectives of this study are to compare clinical and bacterial efficacies and incidence of adverse reactions for topical Ciprofloxacin Ophthalmic Ointment against TOBREX in children (ages 2-12) with acute bacterial conjunctivitis. Acute is defined as having a duration of one week or less.

### TECHNICAL APPROACH:

Materials/methods, subjects, study procedure, etc. outlined in protocol.

### PROGRESS:

Jan 96: Terminated as medication was never received from the drug company and no patients enrolled.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-058

REPORT DATE: 03/01/96

STATUS: Ongoing

TITLE: A Double Blind Evaluation of Ketorolac Tromethamine and Butorphanol Tartrate for the Emergency Department Management of Ureteral Colic

START DATE: 02/25/94

ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Ching, Daniel T.

ASSOCIATE INVESTIGATOR: Mullins, Michael; Coppola, Marco; Karnes, Margaret; Yealy, Donald

DEPARTMENT/SERVICE: Emergency Med

FACILITY: BAMC/DACH

KEY WORDS: Ketorolac Tromethamine, Butorphanol Tartrate, Ureteral colic

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 34

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 34

### OBJECTIVES:

To determine the relative efficacy of ketorolac tromethamine (KT) and butorphanol tartrate (B) for the Emergency Department management of ureteral colic.

### TECHNICAL APPROACH:

To be eligible for this study, all patients must have a diagnosis of acute leukemia or aggressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission. Therapy will follow the schema outlined in the study protocol.

### PROGRESS:

Nov 95: Data being collected.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-098 REPORT DATE: 01/01/95 STATUS: Terminated

TITLE: A Double-Blinded, Randomized Comparison of Viscous Lidocaine Gel for Topical Anesthesia of Dermal Lacerations in Adults

START DATE: 05/04/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Coppola, Marco

ASSOCIATE INVESTIGATOR: Mullins, Michael E; Kietzman, Laurel & Jempsa, James  
(orig PI) have all left DAH

DEPARTMENT/SERVICE: Emerg Med, DAH FACILITY: DAH

KEY WORDS: Lidocaine Gel, viscous cocaine

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To compare a new formulation of viscous cocaine and lidocaine gel for topical anesthesia in the management of dermal lacerations.

### TECHNICAL APPROACH:

To test the safety and efficacy of lower dose heparinization (100 units/kg) in conjunction with a covalently bonded heparin coated (DuraFlow, Edwards Labs) cardiopulmonary bypass circuit in patients undergoing cardiac surgery.

### PROGRESS:

Apr 96: Never started study as the pharmaceutical company never got the dye colors right. (Dr. Coppola)

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-102 REPORT DATE: 09/01/96 STATUS: Completed

TITLE: A Radiographic and Functional Analysis of Short Arm Cast vs Volar Splint Immobilization in Preventing Angulation of Small Finger Metacarpal Neck Fractures

START DATE: 06/01/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Garramore, Jon A.

ASSOCIATE INVESTIGATOR: Frazier, Dustin; Moore, Keith; O'Shea, Thomas; Peterson, Darryl; Spezia, Paul

DEPARTMENT/SERVICE: Surg/Ortho DAH FACILITY: DAH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

We will prospectively evaluate all isolated closed small finger metacarpal neck fractures seen at DACH for loss of anatomic position or reduction during immobilization. We will also compare the effectiveness of cast vs. volar splint immobilization and evaluate hand function following treatment of this fracture using immobilization.

### TECHNICAL APPROACH:

All isolated closed small finger metacarpal neck fractures in patients 18 years of age or older seen by the Orthopedic Surgery Service at DACH will be examined (both physically and radiographically) and treated within one week of the initial injury. Each fracture will be evaluated for pain, tenderness, deformity, neurovascular damage, and hand/finger range of motion.

### PROGRESS:

May 95: Study ongoing; data will be analyzed.

Sep 96: Dr. Darryl Peterson reports that Dr. Garramore completed the study in 95 and a paper was presented.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-128      REPORT DATE: 07/01/96      STATUS: Ongoing

TITLE: Relationships of Smoking Behavior, Health Beliefs, and Health Values to Intentions to Smoke among Pregnant Women in a Military Health Care Setting

START DATE: 08/04/94      ESTIMATED COMPLETION DATE: 01/31/97

PRINCIPAL INVESTIGATOR: Melendez, Leocadio

ASSOCIATE INVESTIGATOR: Planadeball, W.

DEPARTMENT/SERVICE: OB-Gyn DAH

FACILITY: DAH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 153

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 153

OBJECTIVES:

To determine which cognitive variables influence pregnant women intentions to smoke.

### TECHNICAL APPROACH:

Study design, test description, medications used, medical application and further details outlined in protocol.

Questionnaire about smoking and health were filled out by pregnant women in their initial OB registration class.

### PROGRESS:

Jul 96: Data is under statistical analysis and evaluation. Final report is estimated by or before Jan 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-94-141 REPORT DATE: 08/01/96 STATUS: Ongoing

TITLE: Analgesia for Reduction of Acute Glenohumeral Dislocation: Intra-articular Lidocaine Versus Intravenous Fentanyl

START DATE: 09/14/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Coppola, Marco

ASSOCIATE INVESTIGATOR: Gennaro, Victor

DEPARTMENT/SERVICE: Emerg Med

FACILITY: Emerg Med, DAH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 1

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 30

### OBJECTIVES:

To contrast the analgesic efficacy of intra-articular lidocaine vs intravenous fentanyl in an adult population suffering from acute glenohumeral dislocation.

### TECHNICAL APPROACH:

Hypothesize that intra-articular lidocaine is just as an efficacious analgesic for the reduction of acute glenohumeral dislocations as intravenous fentanyl.

### PROGRESS:

Aug 96: Dr. Coppola informs study ongoing; doing preliminary data analysis and found no difference. Have found some doctors being apprehensive in doing the intraarticular anesthesia.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-003 REPORT DATE: 01/01/96 STATUS: Completed

TITLE: Evaluation of a Structured Physical Fitness Program for Pregnant Soldiers: Effects on Weight Gain, Blood Pressure, Lost Duty Time, Length of Labor, Infant Birth Weight, and Score on the First Army Physical Fitness Test (APFT) Post Delivery

START DATE: 11/08/94 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Wanersdorfer, Elizabeth

ASSOCIATE INVESTIGATOR: Gonzalves (Darnall)

DEPARTMENT/SERVICE: Nursing

FACILITY: DAH/FAMC

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 100

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 100

### OBJECTIVES:

To determine whether pregnant soldiers participating in a structured exercise program will have less weight gain, less change in blood pressure, shorter length of labor, higher birth weight babies, less lost duty time, and better ability to pass their first physical fitness test than do pregnant soldiers who do not participate in a structured program. The long term objective is the development of military policy for physical training for pregnant soldiers, contributing to healthier soldiers, healthier babies, and improved military readiness.

### TECHNICAL APPROACH:

Study design, medical application, plan and further details are outlined in protocol.

### PROGRESS:

Nov 95: Enrollment is taking longer than originally anticipated but the goal should be met. Basic data has been loaded into the computer but no significant results are available at this time. At this time have sixty-six percent of the total enrollment. Three have had to drop out of the study for reasons unrelated to the study. Data will not be analyzed until the study is completed.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-006      REPORT DATE: 01/01/96      STATUS: Ongoing  
TITLE: The Efficacy of Nebulized Dexamethasone in the Treatment of Acute Asthma

START DATE: 11/21/94      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Coppola, Marco  
ASSOCIATE INVESTIGATOR: Coppola, Marco

DEPARTMENT/SERVICE: Emerg Med DACH      FACILITY: DACH

KEY WORDS:  
NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:  
To determine the relative efficacy of nebulized albuterol with and without nebulized dexamethasone for the emergency department treatment of acute asthma in an adult population.

TECHNICAL APPROACH:  
Inhaled steroids have been used extensively for the adjunctive outpatient treatment of chronic asthma. However its efficacy in the treatment of acute asthma has not been well established. This investigation will examine if the addition of dexamethasone to nebulized albuterol treatments will provide quicker relief from the acute asthma episode. Other pertinent background info is outlined in protocol.

PROGRESS:  
Nov 95: Dr. DiCiro the original PI has left DACH and therefore Dr. Coppola has become the PI. Of the 19 patients enrolled, going to use them as a pilot study. Have encountered some problems and looking to improve the study. Is currently on hold status. If changes needed will bring back before the Committees.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-032 REPORT DATE: 03/20/96 STATUS: Ongoing

TITLE: Tamoxifen as Treatment for Idiopathic Gynecomastia

START DATE: 03/02/95 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Vikram P. Zadoo

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Surg/Gen Surg FACILITY: BAMC/DACH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 7

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 17

### OBJECTIVES:

To determine if tamoxifen is effective treatment for idiopathic gynecomastia.

### TECHNICAL APPROACH:

Active duty men between the ages of 20 to 40 with gynecomastia are eligible for inclusion into this study. Gynecomastia will be defined as a discrete, nonfibrotic, palpable breast enlargement centered around the periareolar complex. A thorough history, physical exam and pertinent laboratory data will exclude patients with non-idiopathic gynecomastia and patients who are without gynecomastia. If during the physical examination it is difficult to differentiate between gynecomastia and lipomastia, an ultrasound and mammogram will be performed to assist with a correct diagnosis. As fibrous replacement of gynecomastia is usually present for years and this diagnosis may be uncertain on physical examination, patients with gynecomastia for more than 5 years will be excluded from the study.

### PROGRESS:

Mar 96: No adverse affects encountered. Average shrinkage has been shown of 10 sq cm to 2 cm. Anticipate closure in another year with abstract forthcoming.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-95-034      REPORT DATE: 02/22/96      STATUS: Ongoing

TITLE: Comparison of Outpatient Treatments for Pyelonephritis

START DATE: 02/01/95      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Smith, Dennis

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Emerg Med DAH

FACILITY: BAMC/WHMC/DAH

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 8

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 8

### OBJECTIVES:

To supply further evidence that outpatient management of acute pyelonephritis is a safe and effective way to treat a wide range of otherwise healthy men and women. Although many Emergency departments are already treating patients with pyelonephritis on an outpatient basis, there remains contravene about the safety, efficacy, and the population of patients for whom this is safe. This project would attempt to show the population in whom it is safe to treat as an outpatient, as well as safe choices and duration of antimicrobial therapy.

### TECHNICAL APPROACH:

The hypothesis in this study is to prove that outpatient management of healthy individuals with pyelonephritis is both safe and effective using a two week course of either oral plus IV antibiotics or using oral antibiotics alone. Men and women presenting to the Emergency Dept with signs and symptoms suggestive of pyelonephritis will be considered for the study.

### PROGRESS:

Feb 96: Original PI Michael Applewhite has left DAH and Dr. Smith has become PI. No adverse affects encountered. Continuing enrollment (Dr. Coppola).

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-096 REPORT DATE: 07/15/96 STATUS: Ongoing

TITLE: Neurogenic Hypotension in Gulf War Veterans with Chronic Fatigue

START DATE: 08/01/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Davis, Diane

ASSOCIATE INVESTIGATOR: Kator, Polo, Wonnett, Weaver, Sall

DEPARTMENT/SERVICE: Evans ACH

FACILITY: Evans ACH, Ft Carson

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To identify a group of Persian Gulf veterans with symptoms of chronic fatigue not explainable by significant medical or psychiatric problems, quantitate the severity of the fatigue using an analog scale and questionnaire, and to determine the prevalence of neurogenic hypotension as measured by a positive tilt-table test in this group. A control group of active duty soldiers who do not complain of chronic fatigue, and if available, a group of Persian Gulf veterans who do not have chronic fatigue will also undergo tilt-table testing to ascertain the "false positive" rate. Pharmacological treatment of those veterans with chronic fatigue or a positive tilt-table test will not be a part of the study.

### TECHNICAL APPROACH:

Status, medical application, plan, exclusion criteria and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jun 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-108 REPORT DATE: 10/01/96 STATUS: Ongoing

TITLE: **A Randomized Double-Blind, Placebo Controlled Efficacy and Safety Study of Oral Lobucavir in Patients with Recurrent Genital Herpes**

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **McGovern, Thomas W.**

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Derm

FACILITY: Irwin ACH, Ft Riley

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. The time to complete healing defined as the time from therapy initiation to complete re-epithelialization of all genital lesions in subjects with classical genital herpes lesions; 2. The time from therapy initiation to complete resolution of all local signs/symptoms in all subjects, those with classical episodes and those with aborted episodes.

### TECHNICAL APPROACH:

Study design, inclusion/exclusion criteria and detailed specifics are outlined in protocol.

### PROGRESS:

Annual review due Jun 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-109 REPORT DATE: 10/01/96 STATUS: Ongoing

TITLE: **A Randomized double-Blind, Placebo controlled Efficacy and Safety Study of Oral Lobucavir in Patients with Recurent Herpes Labialis**

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: **McGovern, Thomas W.**

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: Derm FACILITY: Irwin ACH, Ft Riley

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. The time to complete healing defined as the time from therapy initiation to complete loss of crust for all herpes oro-labial lesions in subjects with the classical herpes oro-labial lesions; 2. The time from therapy initiation to complete resolution of all local signs/symptoms in all subjects, those with classical episodes and those with aborted episodes.

### TECHNICAL APPROACH:

Study design, inclusion/exclusion criteria and detailed specifics are outlined in protocol.

### PROGRESS:

Annual review due Jun 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-120 REPORT DATE: 09/01/96 STATUS: Ongoing

TITLE: Epidemiology of Prescribed Medication Use Among Active-duty Troops, Retired Soldiers and Their Families

START DATE: 09/07/93 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Remund, Dan

ASSOCIATE INVESTIGATOR: Grabenstein, Potyk

DEPARTMENT/SERVICE: Irwin ACH

FACILITY: Irwin ACH, Ft Riley

KEY WORDS: Epidemiology, medication

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

To quantify use of prescribed medications among active-duty soldiers, retired soldiers, and their families at representative Army posts.

### TECHNICAL APPROACH:

Descriptive report of the incidence and prevalence of use of prescription medications among various groups and subgroups during a 9-month interval. This project is technically exempt from review by a human-use committee, under provisions of 32 CFR 219.101(b)(4). Nonetheless, PI prefers to undergo IRB review to confirm the adequacy of safeguards for protection of patient records involved. LTC Remund or MAJ Grabenstein can be reached at 919-962-7119, fax 966-8486

### PROGRESS:

Sep 96: The Uniformed Svcs Prescription Database Project is a database of prescriptions dispensed from military pharmacies around the US. Its goal is comprehensive drug intelligence on medication use, regardless of health-care setting. The project is conducted by the Pharmacoeconomic Center (PEC), located at FSHT. As of 1 Sep 96 the Uniformed Services Pres Database Project consists of more than 30 million prescription records for more than 2 million people at 27 Army/Navy hospitals and clinics. These average 1.1 million prescriptions and 25 months of observation per site. These medications were ordered by both military and civilian prescribers. This database will gradually grow to include all of the >40 million prescriptions filled at hundreds of military pharmacies each year, plus other prescription programs of the Military Health Service System, including Tricare and CHAMPUS.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-144 REPORT DATE: 10/03/96 STATUS: Ongoing

TITLE: A Prospective Study of the Risk of Stress Fracture in Male Army Recruits During Basic Training

START DATE: 09/10/96 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Kimmel, Donald B.

ASSOCIATE INVESTIGATOR: Lappe, White

DEPARTMENT/SERVICE: Med

FACILITY: Ft Leonard

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

The technical objective of this study is to use quantitative ultrasound of the calcaneus to screen 5424 male Army recruits as they enter basic training at Fort Leonard Wood between 19 Aug 96 and 1 May 97. QUS (UBA575+, Hologic Corporation) is a precise instrument that measures broadband ultrasound attenuation, speed of sound, and velocity of ultrasound.

### TECHNICAL APPROACH:

Will assess the relationship of all QUS variables to stress fracture using logistic regression. Will also collect data that concern various lifestyle risk factors and assess their impact on stress fracture risk, using logistic regression.

### PROGRESS:

Annual review due August 1997.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-113      REPORT DATE: 08/20/96      STATUS: Ongoing  
TITLE: Evaluation of a Phase I Coxiella burnetii Vaccine (IND 610) for Immunization Against Q Fever

START DATE: 01/15/91      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Laraway, John D.

ASSOCIATE INVESTIGATOR: Dey, Julie RN

DEPARTMENT/SERVICE: USA Health Cl

FACILITY: Dugway Proving Ground

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 22  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 65

### OBJECTIVES:

Twofold: 1. Safety - to confirm that the rate of significant, potentially serious reactions to the vaccine is less than 1%. 2. Immunogenicity - to further assess immunogenicity of the vaccine in at-risk personnel (i.e. measurement of specific antibody and lymphocyte response).

### TECHNICAL APPROACH:

Selection of volunteers, study design, risks to participants and detailed specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-114 REPORT DATE: 08/20/96 STATUS: Ongoing

TITLE: Continued Eval of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, TC-83  
Live, Attenuated, NDBR-102, Lot 4 in At-Risk Personnel IND 142

START DATE: 01/15/91 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Laraway, John D.

ASSOCIATE INVESTIGATOR: Dey, Julie RN

DEPARTMENT/SERVICE: USA Health Cl FACILITY: Dugway Proving Ground

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 22  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 65

### OBJECTIVES:

Twofold: 1. Safety - to confirm that the rate of significant, potentially serious reactions to the vaccine is less than 1% for each of these reactions and to estimate the true rates of each reaction. 2. Immunogenicity - to further assess immunogenicity of the vaccine in at-risk personnel.

### TECHNICAL APPROACH:

Administered by US Army Research Institute for Infectious Disease

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-115      REPORT DATE: 08/20/96      STATUS: Ongoing

TITLE: Evaluation of New Lots of Tularemia Vaccine, Protocol B: Comparative Assessment of Francisella tularensis Vaccine, Live, NDBR 101, IND 157

START DATE: 01/15/91      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Laraway, John D.

ASSOCIATE INVESTIGATOR: Dey, Julie RN

DEPARTMENT/SERVICE: USA Health C1      FACILITY: Dugway Proving Ground  
KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 22  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 65

### OBJECTIVES:

To assess the immune response in volunteers vaccinated with either NDBR 101 or TSI-GSD-213 and to compare the results of vaccination with individuals who have previous history of disease or vaccination and with unvaccinated controls.

### TECHNICAL APPROACH:

Methods, risks to participants, and other specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-116 REPORT DATE: 08/20/96 STATUS: Ongoing

TITLE: Eval of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated Protocol B: Contd Assessment of the Safety & Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Lot C-84-6, TSI-GSD 205 as a Booster in At-Risk Personnel IND 914

START DATE: 01/15/91 ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Laraway, John D.

ASSOCIATE INVESTIGATOR: Dey, Julie RN

DEPARTMENT/SERVICE: USA Health Cl FACILITY: Dugway Proving Ground

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 37

### OBJECTIVES:

Twofold: 1. Safety - to establish that the rate of significant, potentially serious reactions to the vaccine is less than 1% for each of these reactions.  
2. Immunogenicity - to further assess the immunogenicity of the vaccine as a booster to the live attenuated vaccine in at-risk personnel.

### TECHNICAL APPROACH:

Methods, selection of volunteers, study design and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-117      REPORT DATE: 08/20/96      STATUS: Ongoing  
TITLE: Administration of Equine Heptavalent Antitoxin for Therapy of Suspected Botulism Intoxication

START DATE: 07/16/91      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Laraway, John D.

ASSOCIATE INVESTIGATOR: Dey, Julie RN

DEPARTMENT/SERVICE: USA Health Cl      FACILITY: Dugway Proving Ground

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 21

### OBJECTIVES:

To provide the depeciated botulinum antitoxin to individuals who may be exposed to botulinal toxins by foodborne, parenteral, or aerosol routes. A secondary objective is the collection of information regarding reactogenicity and efficacy of the product in humans.

### TECHNICAL APPROACH:

Selection of subjects, criteria for exclusion, risks from participation, clinical procedures and further specifics are outlined in protocol.

### PROGRESS:

No report available as of this date. Annual review due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-118      REPORT DATE: 08/20/96      STATUS: Ongoing  
TITLE: Inoculation with Pentavalent (ABCDE) Botulinum Toxoid (CDC IND #161)

START DATE:      /      /      ESTIMATED COMPLETION DATE:      /      /

PRINCIPAL INVESTIGATOR: Laraway, John D.

ASSOCIATE INVESTIGATOR: Dey, Julie RN

DEPARTMENT/SERVICE: USA Health C1

FACILITY: Dugway Proving Ground

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

OBJECTIVES:

Pentavalent (ABCDE) Botulinum Toxoid is a biological product which has been distributed by the Centers for Disease Control (CDC) since 1967. It has been granted an IND status by the Food & Drug Admin, dept of Health and Human Svcs. It is not commercially available in the US. The toxoid itself is free of cost.

TECHNICAL APPROACH:

Inoculation schedule and specifics are outlined in protocol.

PROGRESS:

No report available as of this date. Annual review is due Jul 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-063      REPORT DATE: 04/19/96      STATUS: Ongoing

TITLE: Assessment of Dietary Calcium Intake, Physical Activity and Habits Affecting Skeletal Health Among Premenopausal Military Women

START DATE: 03/20/96      ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: McDermott, Michael T.

ASSOCIATE INVESTIGATOR: Christensen, Reed; Lambert; Albert; Dolan, Donna

DEPARTMENT/SERVICE: Med/Endo

FACILITY: BAMC/FAMC

KEY WORDS: Bone mass, premenopausal, osteoporosis, genetics, calcium intake

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

One objective of this study is to survey a random sample of 2000 premenopausal military women in the continental United States to determine their mean levels and ranges of positive and negative skeletal health factors including calcium intake, physical activity, smoking, alcohol consumption and caffeine consumption. This information will be obtained by means of mailed questionnaires and the data will be tabulated as the questionnaires are returned. The other objective is to determine which skeletal health factors are most highly correlated with the development and maintenance of bone mass at specific skeletal sites.

### TECHNICAL APPROACH:

Peak bone mass, which occurs at approximately age 35 years in women, appears to be an important determinant of the risk of developing postmenopausal osteoporosis. Three factors are considered major contributors to the development of peak bone mass: genetics, calcium intake and physical activity. Additionally a number of adverse risk factors including smoking, alcohol consumption and caffeine consumption may have detrimental effects during this period.

### PROGRESS:

No report available as of this date. Annual review due Feb 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-121 REPORT DATE: 08/21/96 STATUS: Ongoing

TITLE: BioStar Optical Immunoassay for Detection of Group A Streptococcus Directly from Pharyngeal Specimens

START DATE: 12/21/95 ESTIMATED COMPLETION DATE: 03/01/97

PRINCIPAL INVESTIGATOR: Supon, Patrick

ASSOCIATE INVESTIGATOR: none

DEPARTMENT/SERVICE: USA Health C1 FACILITY: Dugway Proving Ground

KEY WORDS: Streptococcus group A, Rapid Streptococcal Testing, Streptococcal

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0

TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. To establish the preliminary performance characteristics of the BioStar Strep A OIA Max Test relative to agar and broth culture.
2. To compare statistically the performance of the test relative to culture.
3. To assess the prevalence and culture density of group A strep in the population of the study site.

### TECHNICAL APPROACH:

This protocol is intended to enroll symptomatic patients presenting with signs and symptoms consistent with pharyngitis. Patients that are enrolled will be swabbed with a single swab and agar culture will be plated and an optical immunoassay run.

100 original specimens approved, increased to 1000 1 Mar 97.

### PROGRESS:

No report available as of this date. Annual review due Jan 97.



## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-122      REPORT DATE: 09/01/96      STATUS: Ongoing  
TITLE: Hypertension Optimal Treatment International Study

START DATE:      /      /      ESTIMATED COMPLETION DATE: 08/01/97

PRINCIPAL INVESTIGATOR: Titzer, Michael

ASSOCIATE INVESTIGATOR:

DEPARTMENT/SERVICE: USA Health C1      FACILITY: Dugway Proving Ground  
KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 25

### OBJECTIVES:

1. To assess the relationship between pooled major cardiovascular events (non-fatal acute and silent myocardial infarction, non-fatal stroke, all cardiovascular deaths) and three target diastolic blood pressures during active antihypertensive therapy. 2. To assess the relationship between pooled major cardiovascular events (non-fatal acute and silent myocardial infarction, non-fatal stroke, all cardiovascular deaths) and the diastolic blood pressure achieved during active antihypertensive therapy. 3. To assess if low dose ASA in addition to antihypertensive therapy reduces pooled major cardiovascular events (non-fatal acute and silent myocardial infarction, non-fatal stroke, all cardiovascular deaths). Etc.

### TECHNICAL APPROACH:

Study aims, eligibility, statistics, etc, outlined in protocol.

### PROGRESS:

Sep 96: Dr. Titzer reports that study is pretty much status quo. Completion date should be about Aug 97.

## DETAIL SUMMARY SHEET

PROJECT NUMBER: C-96-140 REPORT DATE: 09/30/96 STATUS: Ongoing

TITLE: Expanded Safety and Immunogenicity of a Bivalent Oral Attenuated Cholera Vaccine, CVD 103-HgR + CVD111 in Healthy US Adult Volunteers

START DATE: / / ESTIMATED COMPLETION DATE: / /

PRINCIPAL INVESTIGATOR: Taylor, David N.

ASSOCIATE INVESTIGATOR: Dru, Ralph; Johnson, David

DEPARTMENT/SERVICE: NAMRID LimaPeru

FACILITY: US Southern Command

KEY WORDS:

NUMBER OF SUBJECTS ENROLLED DURING REPORTING PERIOD: 0  
TOTAL NUMBER OF SUBJECTS ENROLLED TO DATE: 0

### OBJECTIVES:

1. Determine the safety of the vaccine(s). 2. Determine the immune response to the vaccine(s). 3. Determine the duration of excretion and transmissibility of the vaccine(s). 4. Determine the acceptability and suitability of these single-dose vaccine(s). 5. Determine which vaccine preparation and dose should be used for efficacy trials.

### TECHNICAL APPROACH:

Plan, subjects/study site, inclusion/exclusion criteria, study design and specifics are outlined in protocol.

### PROGRESS:

Due annual review Jun 97.